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Economic Impact Analysis of Proposed Section 5 Notice Requirements. Appendix: Volume I

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Economic Impact Analysis of Proposed Section 5 Notice Requirements

Appendix: Volume I

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Toxic Substances Control Act

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16. ABSTRACT

This report presents the analysis of the economic impact of TSCA section 5 rules on the chemical industry. The industry will be impacted when it introduces new chemicals. Of the six distinguishable consequences for the chemical industry, the most important are the nonquantifiable uncertainty consequences. The more unclear EPA's rationale in making section 5 notice decisions, the greater are the uncertainties.

There will likely be a short-run drop in the number of new chemicals introduced into commerce as chemical companies shift their innovation activities into "safe" chemicals. Current data do not allow a quantitative estimate to be made of the rate of chemical introductions, or the extent of the reduction caused by the section 5 notice requirements; and, even if the data were available, it is doubtful that accurate quantitative predictions could be made.

Smaller companies will face greater uncertainties and the direct costs will more often be a factor in company decisions. In the long run, this regulation may cause the chemical industry to be composed of a fewer number of larger competitors better able to absorb the direct costs and regulatory uncertainty associated with the requirements.

17. KEY WORDS AND DOCUMENT ANALYSIS

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ECONOMIC IMPACT ANALYSIS OF PROPOSED SECTION 5 NOTICE REQUIREMENTS

APPENDIX: VOLUME I

Contract No. 68-01-5878

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PREFACE

The attached document is a contractor's study done with the supervision and review of the Office of Pesticides and Toxic Substances of the U.S. Environmental Protection Agency. The purpose of the study is to analyze the potential economic impact of proposed section 5 notice requirements. These requirements were prepared by the EPA Office of Pesticides and Toxic Substances to implement section 5 of the Toxic Substances Act.

This report was submitted in fulfillment of Task Order Number 3 of Contract Number 68-01-5878 by ICF Incorporated. Work was completed as of August 1980.

This report (consisting of a report and two volumes of appendices) is being released and circulated to coincide with publication in the Federal Register of a notice announcing the availability of the report and of a draft regulatory analysis.

The study is not an official EPA publication. All comments received by EPA will be considered in establishing the final analysis to be published along with the final regulations. Prior to final promulgation of the section 5 requirements, the accompanying document shall have standing in any court proceeding only to the extent that it represents the views of the contractor who prepared it. The document cannot be cited, referenced, or represented in any respect in any such proceedings as a statement of EPA's view regarding the subject, the industry or the economic impact of the regulation.

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APPENDIX A

COST OF FORMS

COST OF FORMS

In order to determine the most effective reporting requirements, EPA sought the costs of various reporting requirements. Originally, Arthur D. Little had estimated the cost of the January 10, 1979 proposed form and the October 16, 1979 reproposed form. ICF was required to estimate the cost of a minimum guidance reporting requirement, processor reporting requirements and importer reporting requirements. The methodologies used for arriving at these cost estimations had been established by Arthur D. Little, Incorporated. Such estimates, along with the methodologies and assumptions behind them, are presented in the following three papers:

- "Cost Estimations of Alternative Processor Notification Requirements,"
- "Estimated Cost of Compliance with the Minimum Guidance Option," and
- "Use of ADL Methodology to Estimate the Cost of the October 1979 Notice Requirement for Importers".

The methodologies and assumptions used in these papers are the foundation for the analysis presented in Chapter V of "Economic Impact Analysis of Proposed Section 5 Notice Requiements; Part 1: Analysis of the Impacts on the Chemical Industry of Proposed Section 5 Notice Requirements."

I. COST ESTIMATIONS OF ALTERNATIVE PROCESSOR NOTIFICATION REQUIREMENTS

This section of the appendix estimates the cost to a company of complying with any of three alternative processor reporting requirements. EPA considered these three alternatiaves as options to the proposed processor requirements outlined in the Federal Register (40 FR 54641). The proposal and these three alternatives would require reporting by persons who process chemical substances exempt from TSCA for a nonexempt commercial purpose. These alternatives differ by the quantity of information processors are required to submit and the cost estimates vary according to this factor. The cost estimates are derived from Arthur D. Little Incorporated's (ADL) projection of the cost of completing the notice form proposed in October 1979. The alternative reporting requirements are:

- Alternative 1: This alternative would require that processors fill out a form which includes company and chemical identity, amount processed, categories of use, name of supplier, worker exposure, consumer exposure, and health and safety data.
- Alternative 2: This alternative would require that some proportion of the reporting firms provide the same information required of manufacturers in the October 1979 proposed form while others provide the information listed in alternative 1.
- Alternative 3: This alternative would require no reporting and thus, would have no direct cost. (The processor would, of course, be subject to other provisions of TSCA which are beyond the scope of this analysis.)

In summary, the costs per submission of each alternative are:

Alternative 1: $724-$4,450

Alternative 2:[a] $724-$4,450

or

$1,155-$8,925

---

[a] Under alternative 2, EPA would select the appropriate notice form for each chemical depending on its potential risk to human health and the environment (Premanufacture Review Program; Proposed Processor Requirements, 45 FR 54642, August 15, 1980).

Alternative 3: $0-$0

In the subsequent pages the derivations of the estimates are explained.

ALTERNATIVE 1

This alternative requires that data on company and chemical identity, amounts processed, categories of use, name of suppliers, worker exposure, consumer exposure, and health and safety be provided.[1]

In order to evaluate the cost of completing a processor notice under alternative 1, estimates must first be made of the number of hours it takes to provide this data. Clerical, technical and managerial personnel are expected to complete this form with the necessary data. Therefore, separate time estimates were obtained for each of these labor categories, and were multiplied by appropriate wage rates to obtain the total cost of filing this notice. The following section explains how the time estimates for managerial and technical personnel were obtained.

Estimation of Technical and Managerial Hours

The number of technical and managerial hours needed to complete a form providing this data was estimated using the following procedure. Each step corresponds to a column in Exhibit AI-1 as indicated.

- Column (a): Identify information requested under alternative 1.
- Column (b): Identify parts of the proposed notice form that are similar to the information requested.
- Column (c): Obtain estimated number of hours needed to complete different parts of the proposed form.[2]
- Column (d): Estimate fraction of these hours required to complete similar parts of the alternative 1 form.[3]

---

[1] Premanufacture Notice: Domestic Manufacturers, 44 FR 59788.

[2] Estimates taken from Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, prepared for the EPA Office of Toxic Substances, September 1979.

[3] For example, if the hours required to complete a certain part of the alternative 1 notice were estimated to be one-half of the hours required to complete the corresponding part of the proposed form, then the estimated fraction would be 0.5. This step is necessary because the information requested under this alternative and under the proposed notice form are not identical.

Exhibit AI-1

Estimated Technical and Managerial Hours for Completing Notice Under Alternative 1

(a) Information Required Under Alternative 1	(b) Comparable Parts in Section 5 Notice	(c) ADL Time Estimate for Completing Section 5 Notice (Hours)		(d) Fraction of ADL Estimate Attributable to Providing Information Required Under Alternative 1		(e) Time Estimate for Completing Notice Under Alternative 1 (Hours)	
		Technical	Managerial	Technical	Managerial	Technical	Managerial
Certification Statement	General Certification and Confidentiality Certification	0	0	--[1]	--[1]	0	0
Company Name/Address and Technical Contact Name/Address/Phone	Part I. General Information A. Manufacturer Identification (Contains Intended Manufacture Date and Prenotice Communication Number in Additional to Form E Required Information)	0	1-8	--[1]	N/A[2]	0	0-1
Chemical Name, Structural Information, and Supplemental Information	Part I. General Information B. Chemical Identity 1. Class I Chemical Substance 2. Class II Chemical Substance 3. Polymers	1- 5	0	1	--[1]	1- 5	0
Amount Processed	Part II. Human Exposure and Environmental Release A. Industrial Sites Controlled by the Submitter 1. Process Information (Includes Identity of Site, Type of Site, Hours of Operation, Amount Processed)	1- 4	2-6 for entire Section A	0.5	0	0.5- 2	0
Categories of Use	Part I. General Information D. Production and Marketing Data 2. Category of Use	1- 8	1-2 for entire Section D	1	0.25	1- 8	0.25-0.5
Name of Supplier	Part II. Human Exposure and Environmental Release B. Industrial Sites Controlled by Others 1. Process Information--Identity of Site	0- 2	0-2 for entire Section B	1	0	0- 2	0
Worker Exposure	Part II. Human Exposure and Environmental Release A. Industrial Sites Controlled by Submitter 3. Occupational Exposure	4-32	2-6 for entire Section A	1	0.5	4-32	1-3
Consumer Exposure	Part II. Human Exposure and Environmental Release C. Consumer and Commercial User Exposure	0-28	0-2	1	1	0-28	0-2
Health and Safety Data	Part III. List of Attachments A. Physical and Chemical Properties Data B. Health and Environmental Effects Data	12-56	3-12	1	1	12-56	3-12
Total Hours Under Alternative 1						18.5-133	4.25-18.5

---

[1] These fractions were not estimated because, regardless of what they might have been, they would have had no effect on the final cost estimation. This is consistent with the fact that any number multiplied by zero is equal to zero.

[2] Because of a peculiarity in the set of questions found in the comparable parts of the section 5 notice, this fraction was not estimated. The managerial hours for completing this part of the Alternative 1 notice was estimated through direct examination of the Alternative 1 and section 5 questions. This estimation procedure is explained in the text.

- Column (e): Multiply ADL time estimates by ICF estimate of fraction of time required to complete alternative 1 data requirements.

Total:

- Calculate sum of these products to obtain total technical and total managerial hours needed to provide information requested under alternative 1.

Estimation of Fractions

For each alternative 1 notice requirement, there was a similar part of the proposed form for which ADL estimated technical and managerial hours. Each part of the proposed form was chosen so that it incorporated all of the information requested in the corresponding part of the alternative 1 requirements. Therefore, the technical and managerial hours needed to complete the proposed form part would always be at least as great as the number of hours needed to complete the corresponding part of alternative 1 notice requirements. In some cases, the hours needed to complete each proposed form part could be much greater than the hours needed to complete the corresponding alternative 1 part.

Each part of the Alternative 1 notice was assigned a fraction of the ADL estimates for technical and managerial hours. The fraction represents that portion of the ADL estimated hours needed to complete the counterpart sections of the alternative 1 notice. For example, ADL estimated it would take from one to four technical hours to complete a portion of the proposed form notice related to process information. This particular portion of the form requests information on site identity, site type, hours of operation, and amount processed. However, alternative 1 would require information only on amount processed. Thus, the number of technical hours required to complete that portion of the alternative 1 notice is only a fraction of the ADL estimate for the proposed form. In this case, the fraction assigned was 0.5, or one-half of the estimated proposed form hours.

The following discussion explains the methodology used to estimate the fractions. Each part of the Alternative 1 notice is considered separately.

1. Certification Statement. The certification statement for Alternative 1 is quite similar in purpose and function to the general certification and confidentiality certification statements of the proposed form. Both require an authorized official to sign and date the form.

ADL did not include the certification statement in its cost estimate and, therefore, did not assign to it any time estimates, zero or otherwise. In so doing, ADL effectively attributed zero technical and zero managerial hours to the certification statement. Thus, in being consistent with ADL's costing methodology, zero technical and zero managerial hours were assigned here as well.

Because zero hours were assigned, the fraction of time needed to complete the certification statement was not estimated. Regardless of what the fraction is, the number of hours needed to complete this part of the alternative 1 notice would be zero.

2. Company Name/Address and Technical Contact Name/Address/Phone. This information, as required in alternative 1, was comparable to the information requested in Section I(A) of the form proposed in October. The submitter must provide its name and address and identify a technical contact. The comparable proposed form data also requires identification of the parent company and intended date of manufacture. To this proposed form subsection, ADL assigned zero technical hours and 1-8 managerial hours. The eight-hour maximum was assumed to be mostly attributable to supplying intended date of manufacture, while the rest of the section required only about an hour to complete. The company name and technical contact information requested in alternative 1 required between 0 and 1 hours of managerial time, and no hours of technical time.

3. Chemical Name, Structural Information, and Supplemental Information on Chemical Identity. The alternative 1 requirements and the requirements of the proposed form are identical. Therefore, the corresponding fractions were estimated to equal 1.

4. Amount Processed. The part of the proposed form that requests this information requests identity of the site, type of site, hours of operation, and amount manufactured, processed, or used. Only two questions would require a significant amount of time to complete: hours of operation, and amount manufactured, processed, or used. These questions are dependent on each other. It was estimated that each would take about the same amount of time, on the average, to answer. Therefore, the fraction of technical time attributed to the question on amount processed was 0.5. The amount of managerial time required to complete this section was assumed to be zero because 30 minutes to two hours of technical time (see column e of Table 1) was considered sufficient to provide information on the amount processed.

5. Categories of Use. The alternative 1 requirements with respect to this part are identical to the requirements in subsection I(D)(2) of the proposed form.[4] Thus, one hour of technical time is estimated for this section. ADL did not provide a separate estimate for the amount of managerial time required to complete subsection I(D)(2), Category of Use. Instead, ADL estimated it would take from two to six managerial hours to complete the entire section I(D). A comparison of the subsections of I(D) provides an estimate of the fraction of time it would take to answer I(D)(2) independently from the other subsections. Specifically, the length of time it would take to answer I(D)(2) was estimated to be roughly the same as the amount of time it would take to answer each of the following subsections: I(D)(1), I(D)(4), and I(D)(5). The amount of time needed to answer I(D)(3) is assumed to be negligible relative to the other four subsections.

---

[4] Statement by Ken Gray of the U.S. Environmental Protection Agency, March 1980.

Thus, there are four major parts - I(D)(1), (2), (4), and (5) - that take about the same amount of time to answer. In other words, it would take approximately one-fourth of the total time required to complete the entire I(D) to answer subsection I(D)(2). Therefore, a fraction of 0.25 was estimated for managerial hours.

6. Name of Supplier. Subsection II(B)(1) of the proposed form required information comparable to that required in the alternative 1 notice. Thus, the fraction of technical hours attributed to completing the section on supplier's name was one. Because providing this information appeared to require no managerial time, the fraction was estimated to be zero.

7. Worker Exposure. The Alternative 1 requirements with regard to worker exposure are exactly those requested in subsection II(A)(3), Occupational Exposure, of the proposed form. Thus, the fraction of technical hours attributable to the alternative 1 requirements was estimated to be one.

The managerial hours for the subsection of the proposed form notice, however, were not estimated by ADL. We estimated the subsection after examining the entire section (II(A)) for which ADL had made an estimate. This section contains four subsections: Process Information, Block Diagram, Occupational Exposure, and Environmental Release and Disposal. Subsection 1 (process information) was considered negligible with respect to required managerial hours, as was subsection 2 (the Block Diagram), which required purely technical information. Subsection 4 (environmental release and disposal) was considered to require roughly the same amount of managerial hours as the subsection 3 (occupational exposure). Thus the total managerial hours of the section could be divided equally between subsection 3 and subsection 4. As a result, the fraction of managerial hours in Section II(A) attributable to alternative 1 requirements on occupational exposure was estimated to be 0.5.

8. Consumer Exposure. The information requirements of alternative 1 with respect to this category were defined to be those information requirements in section II(C), Consumer and Commercial User Exposure, of the form proposed in October. Therefore, the fractions were set at one for each labor category.

9. Health and Safety Data. The information requirements of Alternative 1 with respect to this category were defined to be those information requirements in section III(A), Physical and Chemical Properties Data, and III (B), Health and Environmental Effects Data, of the October proposed form. Therefore, the fractions were set at one for each labor category.

Range of Technical and Managerial Hours

As shown in Exhibit AI-1 column(e) on page 4 the total technical hours range from 18.5-133. The total managerial hours range from 4.25-18.5. These values represent the sum of the costs of the component parts.

Estimation of Clerical Hours

Using ADL's time estimates for the section 5 notice,[5] we computed the ratios of clerical to technical and clerical to managerial hours. The ADL time estimates for the proposed form, by labor category, ranged as follows:

Clerical	8 - 40 hours
Technical	27 - 267 hours
Managerial	8 - 37 hours

The ratios of minimum hours that appear in Exhibit AI-2 are simply the ratios of the ADL lower bound estimates. Similarly, the ratios of maximum hours are the ratios of the ADL upper bound estimates.

In order to estimate clerical hours, the ratios were multiplied by the estimated total technical and managerial hours needed to provide the information required by alternative 1. For example, the 5.48 minimum hours estimate in Table 3 was obtained by multiplying .296 times 18.5 (the estimated minimum technical hours to complete the alternative 1 notice). Once estimates of the clerical hours were obtained in this fashion, an average was computed to obtain an estimate of the number of clerical hours required to complete the notice. That is, 5.48 plus 4.25, divided by two equals 4.87 (see Exhibit AI-3. The estimated average ranged from 4.87 to 19.97 hours of clerical time.

Exhibit AI-2

Ratios of Clerical to Technical and Managerial Hours

Ratio	Ratio of Minimum Hours	Ratio of Maximum Hours
Clerical Hours to Technical Hours	.296	.150
Clerical Hours to Managerial Hours	1.00	1.08

---

[5] Table 4, Chapter VI, of Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, September 1979.

Exhibit AI-3

Estimated Clerical Hours

	Minimum Hours	Maximum Hours
Based on Clerical to Technical Hours Ratio	5.48	19.95
Based on Clerical to Managerial Hours Ratio	4.25	19.98
Approximate Average	4.87	19.97

Estimation of the Total Cost of Completing an Alternative 1 Notice

To estimate the total cost of completing a notice under alternative 1, the average hourly wage rates by labor category were multiplied by the respective number of hours needed to complete a notice. The average hourly wages were the same as those established by ADL: $10/hour clerical, $25/hour technical and $50/hour managerial. The results are presented in Exhibit AI-4. The total cost of preparing and submitting a notice under alternative 1 ranged from $724 to $4,450.

Exhibit AI-4

Cost of Completing Alternative 1 Notice

Labor Category	Estimated Hours to Complete Alternative 1 Notice		Average Wage Rate	Estimated Cost of Completing Alternative 1 Notice	
	Minimum	Maximum		Minimum	Maximum
Clerical	4.87	19.97	$10	$48.70	$199.70
Technical	18.50	133.00	$25	$462.50	$3,325.00
Managerial	4.25	18.50	$50	$212.50	925.00
Total				$723.70	$4,449.70
				or	
				$724	$4,450

ALTERNATIVE 2

Alternative 2 would require processors of exempt substances for nonexempt commercial purposes to submit one of two different types of notification. The first type of notification would consist of those data requirements specified in the Federal Register notice "Proposed Processor Requirements." EPA proposed data requirements for processors that, with minor additions, are the same as those proposed in October for domestic manufacturers. ADL estimated that the cost of submitting the October proposed form ranged from $1,155 to $8,925.[6] The other type of notification a processor could be required to file under this alternative consists of that information as outlined in alternative 1. ICF's estimates for the cost of alternative 1 notification range from $724 to $4,450.

The following equation may be used to estimate the range of costs when a fraction of processors file the information required by the processor proposal and the remainder file information required by alternative 1. The variable X represents that fraction of all exempt substances processed for nonexempt purposes that would be subject to the information requirements specified in the July processor proposal.

Estimated Range of Notification Costs for Alternative 2 =

$$(X)\begin{bmatrix}\text{ADL's Estimated Cost Range}\\ \text{for Section 5 Notification}\end{bmatrix} + (1-X)\begin{bmatrix}\text{Estimated Cost Range for}\\ \text{Alternative I Notification}\end{bmatrix}$$

$$\text{ERNC} = (X)\ (\$1{,}155 \text{ to } \$8{,}925) + (1-X)(\$724 \text{ to } \$4{,}450)$$

$$\text{ERNC} = (X)(\$1{,}155) + (1-X)(\$724) \text{ to } X(\$8{,}925) + (1-X)(\$4{,}450)$$

Example: Suppose only 10 percent of all exempt substances used for nonexempt purposes were subject to the requirements proposed for processors in the Federal Register. Then:

$X = .10$

The estimated range of notification costs for alternative 2 would then be $767 - $4,898.

Unfortunately, we have no information about the actual percentage. Thus, it is impossible to estimate the average cost per submission.

ALTERNATIVE 3

This alternative does not require any reporting, therefore, the cost of this alternative is zero. Unfortunately, we have no information about the actual percentage. Thus it is impossible to estimate the average cost per submission.

---

[6] Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, September 1979.

II. ESTIMATED COST OF COMPLIANCE WITH THE MINIMUM GUIDANCE OPTION

DETERMINATION OF REQUIRED INFORMATION

In this paper, we assign costs to submitting a section 5 notice when EPA does not provide a form, but does provide minimum reporting guidance. The information required under a minimum guidance scheme is organized into the following categories: Manufacturer's Identity, Chemical Identity, Use Categories and Amount Produced per Use Category, Byproducts, Occupational Exposure, Method of Disposal, Health and Environmental Effects Data, and *Federal Register* Notice. For each of these categories we describe the information required. This required information, by category, is displayed in Exhibit AII-1.

Exhibit AII-1
Submission Requirements under Minimum Guidance Reporting

1. Chemical Identity: Included in the data would be specific chemical name, CAS#, or molecular formula with structural diagram; and specific identification of monomers at least to the two percent level.

2. Use Categories and Amount Produced per Use Category: Included in these data would be amount produced per use category, types and levels of exposures, decriptions of use, and some consumer exposure information.

3. Byproducts: These data would include a list of significant byproducts at each stage in the substance's life cycle, including manufacturing, processing, use, and disposal.

4. Occupational Exposure: This information would include the number of workers, type and degree of exposure, and duration of exposure (duration of daily exposure and duration of cumulative exposure by month or year) expected. Information both on the submitter's work sites and work sites controlled by others would be expected.

5. Method of Disposal: These data should include the identity of the site where the submitter, and others known by the submitter, intend to dispose of the new substance. They should also include the duration of release, mode of release, media into which release occurs (air, water, land), amount released, and pollution control equipment used in the disposal operations.

6. Federal Register Notice: This notice would include a name for the chemical (actual or generic), manufacturer's identity (actual or masked), categories of use (actual or masked), and test data.

7. Manufacturer's Identity: These data would include the organization's name, the name and address of the person filing the notice, the technical contact's name and address, the parent organization's name and address, and the intended date of manufacture for commercial purposes.

8. Health and Environmental Data: Included here would be data on risk assessment, detection methods, environmental release and disposal, consumer and commercial user exposure, physical and chemical properties, and health and environmental effects.

COSTING METHODOLOGY

A. OVERVIEW

ADL's costing methodology for the October reproposed form[1] is used as a basis for the costing of the minimum guidance reporting requirements. The reasons we chose this as the starting point are:

1. In its costing of the reproposal, ADL outlined the costs per requirement category in detail. This allowed us to assign costs accurately to similar requirement categories under the minimum guidance option.

2. The reproposed form was the most recent source of detailed cost data, and therefore contained the most accurate information about costs.

3. Without specific guidance from the agency, submitters will tend to err on the side of a narrow interpretation of statutory requirements.

In order to estimate the cost of meeting the requirements of the section 5 notice minimum guidance option, estimates are first made of the number of hours necessary to provide the information. It is expected that providing the required information will involve clerical, technical, and managerial personnel. Therefore separate time estimates are given for each of these labor categories. The time estimates are multiplied by appropriate wage rates to obtain an estimate of the total cost. The following section explains how the time estimates for managerial and technical personnel are obtained.

B. ESTIMATION OF TECHNICAL AND MANAGERIAL HOURS

The number of technical and managerial hours needed to comply with the minimum guidance option are shown in Exhibit AII-2 and were estimated by the procedure described below.

- Step 1: List each information category (or submission requirement).

- Step 2: Identify parts of the reproposed form which contain all of the information required by the corresponding submission requirements under the minimum guidance option.

---

[1] The "reproposed form" or "reproposal" refers to the TSCA section 5 notification form entitled "EPA Premanufacture Notice: Domestic Manufacturers," proposed on October 16, 1979, in the Federal Register, 44 FR 59788.

Exhibit AII-2

Estimation of Required Technical and Managerial Hours

a	b	c		d		e	
Minimum Guidance Option Submission Requirements	Parts of Reproposed Form Comparable to Submission Requirements	ADL's Estimated Hours For Completion of Section 5 Parts		Fraction of Those Hours Needed to Complete Minimum Guidance Option Submission Requirements		Hours Needed to Complete Minimum Guidance Option Submission Requirements	
		Technical	Managerial	Technical	Managerial	Technical	Managerial
Chemical Identity	I. General Information B. Chemical Identity 1. Class 1 Chemical Substance 2. Class 2 Chemical Substance 3. Polymers	1-5	0	1	--	1-5	0
Use Categories and Amounts/Use Category	I. General Information D. Production and Marketing Data 1. Production Volume 2. Category of Use	2-12	1-2 for entire section D	1	.5	2-12	.5-1
	II. Human Exposure and Environmental Release C. Consumer and Commercial User Exposure 1. Table - Route, Frequency and Number Exposed	0-16	0-2 for entire section C	1	.25	0-16	0-.5
Byproducts	II. Human Exposure and Environmental Release A. Industrial Sites Controlled by the submitter	1-24		.6		.6-14.4	
	2. Block Diagram		2-6 for entire section A		.17		.3-1
	3. Occupational Exposure 3.5 Other Substances	2-16 for subsections 3..3-3.5		.5		1-8	
	C. Consumer and Commercial User Exposure 4. Byproducts of Use	0-4	0-2 for entire section C	1	.25	0-4	0-.5

Exhibit AII-2 (continued)

Estimation of Required Technical and Managerial Hours

a Minimum Guidance Option Submission Requirements	b Parts of Reproposed Form Comparable to Submission Requirements	c ADL's Estimated Hours For Completion of Section 5 Parts		d Fraction of Those Hours Needed to Complete Minimum Guidance Option Submission Requirements		e Hours Needed to Complete Minimum Guidance Option Submission Requirements	
		Technical	Managerial	Technical	Managerial	Technical	Managerial
Occupational Exposure	II. Human Exposure and Environmental Release A. Industrial Sites Controlled by the Submitter 3. Occupational Exposure 3.1 Identity of Site	2-16 for subsections 3.1-3.2	2-6 for entire section A	1	.33	2-16	.7-2
	3.2 Occupational Exposure at Site 3.3 Direct Exposure 3.4 Physical State	2-16 for subsection 3.3-3.5		.5	-	1-8	-
	B. Industrial Sites Controlled by Others 3. Occupational Exposure	0-20	0-2 for entire section B	1	.5	0-20	0-1
Method of Disposal	II. Human Exposure and Environmental Release A. Industrial Sites Controlled by Submitter 4. Environmental Release and Disposal	1-12	2-6 for entire section A	1	.5	1-12	1-3
	B. Industrial Sites Controlled by Others 4. Environmental Release and Disposal	0-8	0-2 for entire section A	1	.5	0-8	0-1
Federal Register Notice	IV. Federal Register Notice	1-8	1-2	1	.5	0-8	0-1

EXHIBIT AII-2 (continued)

Estimation of Required Technical and Managerial Hours

a	b	c		d		e	
		ADL's Estimated Hours For Completion of Section 5 Parts		Fraction of Those Hours Needed to Complete Minimum Guidance Option Submission Requirements		Hours Needed to Complete Minimum Guidance Option Submission Requirements	
Minimum Guidance Option Submission Requirements	Parts of Reproposed Form Comparable to Submission Requirements	Technical	Managerial	Technical	Managerial	Technical	Managerial
Manufacturer Identification	I. General Information A. Manufacturer Identification	0	1-8	--	1	0	1-8
Health and Environmental Data (Not Previously Listed)	I. General Information						
	F. Risk Assessment	0-16	0-2	1	1	0-16	0-2
	G. Detection Methods	1-4	0	1	--	1-4	0
	II. Human Exposure and Environmental Release C. Consumer and Commercial User Exposure						
	2. Exposure Levels	0-4	0-2 for entire section C	1	.5	0-4	0-1
	3. Product Aspect Affecting Consumer Exposure	0-4		1	--	0-4	--
	III. List of Attachments						
	A. Physical and Chemical Properties Data	4-16	1-4	1	1	4-16	1-4
	B. Health and Environmental Effects Data	8-40	2-8	1	1	8-40	2-8
	TOTAL HOURS NEEDED TO COMPLETE MINIMUM GUIDANCE OPTION SUBMISSION REQUIREMENTS					22.6-215.4	7.5-35.0

Exclude all reproposal parts that have previously been listed in the column (so as to avoid the double-counting of required information).

- Step 3: Give the estimated number of hours needed to complete the listed parts of the reproposed form.[2]
- Step 4: Estimate the fractions of these hours required to provide the information under the minimum guidance option.[3]
- Step 5: Multiply the hours estimates of column c (for reproposal parts) by the fraction estimates of column d to yield time estimates for the minimum guidance option. Then, calculate the sum of these products to obtain the total technical and managerial hours needed to supply information required under the minimum guidance option.

Two of the five steps required decision making on the part of ICF: the listing of the parts of the reproposed form comparable to the minimum guidance option (column b), and the estimation of the ratio of hours required to provide categories of information under the minimum guidance option to hours required to complete the comparable part of the reproposed form. The rationale behind these decisions is presented below for each type of information, and they should be read in conjunction with Exhibit AII-2.

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[2] Estimates taken from Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, prepared for the EPA Office of Toxic Substances, (Cambridge, Mass.: September 1979).

[3] For example, if the hours required to provide a certain category of information were estimated to be one-half the hours required to complete the corresponding part of the reproposal, then the estimated fraction would be 0.5. This step is necessary because the information requested under the minimum guidance option and the information requested under the reproposal may not be identical.

It would not take more time to complete a given category of information under the minimum guidance option than to complete the corresponding reproposal part, because each reproposal part was designed to incorporate all of the information in the minimum guidance option.

1. Chemical Identity. The minimum guidance option requires specific chemical name; CAS# or molecular formula with structural diagram; and the specific identification of monomers, at least to the two percent level. The subsections of the reproposed form containing this information are I.B.1., I.B.2., and I.B.3. Because the reproposed sections do not require substantially more technical information than what is required under the minimum guidance option, it was estimated that the technical hours for either notice would be about the same. Thus, the minimum guidance technical hours were assumed equal to the reproposal hours. Since the managerial hours were zero, there was no need to estimate a fraction for managerial hours.

2. Use Categories and Amount Produced per Use Category. The minimum guidance option requires: amount produced per use category; types and levels of exposure; descriptions of use; and use and some consumer exposure information. The subsections of the reproposed form containing this information are I.D.1., I.D.2., and II.C.1. Unlike the minimum guidance option, the reproposed policy did not specifically request the quantity produced per use category. It did request, however, both the total quantity produced, in subsection I.D.1., and the production percent per use category, in subsection I.D.2. Because such information can easily be used to derive the quantity produced per use category, subsections I.D.1. and I.D.2. were included in the costing of the present submittal requirement.[4] Types and levels of consumer exposure, provided in subsection II.C.1., were also included. Occupational exposure, however, will be discussed and included in the costing of the occupational exposure requirement.

Technical hours: Except for question 2(c), all of the information requested in subsections I.D.1., I.D.2., and II.C.1. of the reproposed form appears to be required under the "use categories and amounts produced per use category" of the minimum guidance reporting option. The time needed to complete question 2(c) appears to be negligible relative to the time needed to complete the rest of the subsection. For these reasons, it was estimated that the number of hours needed to complete the three subsections would be about the same as the number of hours needed to provide the information under the the minimum guidance option. Therefore, technical hours for the minimum guidance option were set equal to the hours estimated for these subsections of the reproposal.

Managerial hours: The number of managerial hours for the subsections were not provided in ADL's costing analysis. However, information was available pertaining to the managerial hours estimated for the entire section I.D., and the managerial hours estimated for the entire section II.C. To estimate the managerial hours needed under the minimum guidance option to provide the information contained in the subsections, the proportions of each section's managerial hours that could be attributed to the required subsections had to be estimated. (This was consistent with the estimate that the information provided under the minimum guidance option was essentially the same as that in the subsections.)

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[4] Quantity produced times the percent production per use category equals the quantity produced per use category.

Section I.D. has three other subsections: I.D.3.--Previous Manufacture; I.D.4.--Hazard Warnings; and I.D.5.--Number of Customers. Subsection I.D.3., which required a yes, no, or don't know response to the question, "Has the chemical substance been manufactured before?", would require an insignificant amount of managerial time to complete. Subsections I.D.4. and I.D.5. seemed to be roughly comparable, in the managerial hours that they might require, to subsections I.D.1. and I.D.2. Therefore, the estimate was made that subsections I.D.1. and I.D.2. together constituted about one-half of section I.D. in terms of required managerial hours. As a result of this estimate, the fraction 0.5 was determined to be the fraction of section I.D. managerial hours necessary to provide information under the minimum guidance option.

This same methodology was used to estimate the fraction of managerial hours for section II.C. that would be required to provide information under the minimum guidance option. Section II.C. was composed of the subsections II.C.1.--Table--Route, Frequency and Number Exposed; II.C.2.--Exposure Levels; II.C.3.--Product Aspect Affecting Consumer Exposure; and II.C.4.--Byproducts of Use. Since all of these sections were estimated to be comparable in terms of managerial time required, a fraction of 1/4 (or 0.25) was determined to reflect the managerial hours for subsection II.C.1.5/

3. Byproducts. The minimum guidance option requires a list of significant byproducts at each stage in the substance's life cycle including manufacturing, processing, use and disposal. It is assumed that more information (e.g., amounts generated) would be provided for those products perceived to be more harmful. The subsections of the reproposal containing similar information were those relating to the amount produced, the origin and the release of each major byproduct (subsection II.A.2); those concerning occupational exposure to byproducts (subsection II.A.3.5); and those concerning consumer exposure (II.C.4).

Technical hours related to major byproducts: It was estimated that the technical hours required to complete the information on byproducts in subsection II.A.2. would be about 60 percent of the technical hours required to complete the entire subsection. This rough estimate was based on the following rationale:

- It was estimated that the technical hours required to (1) identify the major unit operations and chemical conversions, and (2) to provide the approximate mass of all feed materials, byproduct materials, and products entering and leaving each major unit

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5/Because the minimum guidance option incorporated all of section II.C., section II.C. would have always contributed the range of 1-2 managerial hours to the total hours required for the completion of the minimum guidance option. However, fractions were determined for section II.C. in order to maintain a consistent methodology.

operation and chemical conversion, were about the same, and that they were about twice the hours required to identify those points in the block diagram from which there would be releases of the new chemical substance or byproducts into the environment.

- Thus, the ratio of the technical hours required to complete parts of subsection II.A.2. corresponding to the items mentioned above were 2:2:1, respectively.
- It was further estimated that, on the average, the technical hours needed under the minimum guidance option to provide information on byproducts would be about half the time needed to (1) identify the major unit operations and chemical conversions, and (2) to provide the approximate mass of all feed materials, byproduct materials, and products entering and leaving each major unit operation and chemical conversion, and would be almost all of the time needed to identify those points in the block diagram from which there would be releases of the new chemical substances or byproducts into the environment.
- The above estimate translates into the statement that providing information on byproducts under the minimum guidance option would take about one-half of two-fifths, plus one-half of another two-fifths, plus almost an entire fifth of the technical hours attributed to the subsection.
- Therefore, the estimated fraction of technical hours was (1/2)(2/5) + (1/2)(2/5) + (1)(1/5) = 0.6.

Technical hours related to occupational exposure to byproducts: The technical hours required to provide information on occupational exposure to byproducts were estimated to be about one-half the hours for all of II.A.3.3 to II.A.3.5. of subsection II.A.3. Because only occupational exposure data were sought, the fraction of technical hours listed for subsection II.A.3.5 was 0.5 (see Table 2).

Managerial hours related to the above two topics: It was assumed that relatively little managerial time would be spent on subsection II.A.2. (Block Diagram) since the information contained in this subsection was primarily technical. For this reason, it was assumed that the vast majority of managerial hours for section II.A. would be spent on subsection 3, Occupational Exposure, and on subsection 4, Environmental Release and Disposal. Subsection 3 was estimated to require about the same number of managerial hours as subsection 4. Thus, about half of all the managerial hours for section II.A. would be spent on subsection 3.

Three of the five questions in subsection 3 (3.2, 3.3, and 3.5) seemed to require roughly the same number of managerial hours, while questions 3.1 and 3.4 appeared to require relatively few managerial hours. For these reasons, question 3.5 was estimated to require about one-third of the managerial hours needed for subsection 3. Since subsection 3 required about one-half of the managerial hours needed for section II.A., it followed that question 3.5 required about one-third of one-half, or one-sixth, of the managerial hours for section II.A. Because subsection II.A.2. was considered primarily technical, it was ignored in the estimation of managerial hours. In conclusion, the managerial hours for providing the information in section II.A. under the minimum guidance option were estimated to be one-sixth, or 0.17 of the hours for the entire section.

Technical and managerial hours related to consumer exposure to byproducts: Subsection II.C.4. was determined to require information that was clearly called for under the minimum guidance option. Therefore, the fraction of the technical hours assignable to minimum guidance was clearly 1. As previously stated, it was estimated that the four subsections of section II.C. were roughly comparable in terms of managerial hours. It follows that the fraction of section II.C. managerial hours needed for subsection II.C.4. would be one-fourth, or 0.25. Since ADL provided managerial hours only for the entire section II.C., the managerial hours for II.C.4. were taken as 0.25 of those hours.

4. Occupational Exposure. The minimum guidance option calls for information on work sites other than the submitter's in addition to information on the submitter's work sites; number of workers and duration of exposure (duration of daily exposure and duration of cumulative exposure by month or year); and the type and degree of exposure (Exhibit AII-2). The subsections of the reproposal that contained this information and that were not counted previously were related to occupational exposure at both the submitter's work site and at work sites controlled by others. Work sites where substances are made under contract to submitters would be excluded.

From examination of the subsections of the reproposal that require similar information (I.A.3.1., II.A.3.2., II.A.3.3., II.A.3.4., II.B.3.), it is clear that they call for the same information that is specified in the minimum guidance option. Because all of the data in these subsections are required under the minimum guidance option, the fraction of the technical hours needed to complete submission requirements was 1. As already discussed,[6] subsections II.A.3.3 and II.A.3.5 were each estimated to require approximately one-half of the technical hours needed to complete subsection II.A.3. Therefore, the technical hours for subsections 3.3 to 3.4 was estimated to be .5 of those hours attributed to subsections 3.3 to 3.5.

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[6] See discussion of subsection II.A.3.5 in "3. Byproducts".

Also discussed previously was the estimate that subsection II.A.3. constituted about one-half of the managerial hours for section II.A., and that subsection II.A.3. (3.5) constituted about one-third the managerial hours for subsection II.A.3. Since II.A.3. consisted entirely of II.A.3. (3.1 to 3.5), it followed that subsections II.A.3. (3.1 to 3.4) constituted two-thirds of the managerial hours for subsection II.A.3. Thus, the managerial hours for subsections II.A.3. (3.1 to 3.4) were one-half of two-thirds of the hours attributed to all of section II.A., and so the estimated fraction was .33.

Managerial hours related to occupational exposure at work sites controlled by others: Section II.B. requires kinds of data similar to those required in section II.A., except that the data is for work sites not controlled by the submitter instead of sites that the submitter controls. Thus, the estimates of the proportion of managerial hours required for each part were derived as discussed previously for section II.A. Subsections II.B.1. and II.B.2. require virtually no managerial time. Subsections II.B.3. and II.B.4., however, each appear to require a substantial amount of managerial time, and the hours for each seem to be about the same. It was estimated, then, that the fraction of section II.B. managerial hours attributable to subsection II.B.3. was 0.5.

5. Method of Disposal. The minimum guidance reporting option calls for the identity of the site where the submitter and others known to the submitter intend to dispose of the new substance. It should also include the duration of release; mode of release; media into which release occurs (air, water, land); amount released; and pollution control equipment used in the disposal operations. This is virtually identical to subsections II.A.4. and II.B.4. of the reproposal form.

As previously stated, it was estimated that in the reproposal subsections II.A.3. and II.A.4. each required about one-half of the managerial hours needed for all of section II.A., and that subsections II.B.3. and II.B.4. required the same with respect to section II.B. Therefore, the fractions of the managerial hours for sections II.A. and II.B. attributable to subsections II.A.4. and II.B.4., respectively, were estimated to be 0.5. Since ADL provided estimates of technical hours for these subsections, and since these subsections constituted the minimum guidance reporting, the fraction of listed technical hours needed to complete these requirements was 1 for each subsection.

6. Federal Register Notice. The minimum guidance reporting option requires the same Federal Register notice that is required in part IV of the reproposal (Exhibit AII-2). This would include a name for the chemical (actual or generic); manufacturer's identity (actual or masked); categories of use (actual or masked); and test data. The technical and managerial hours for this part were estimated by ADL, and so the fractions corresponding to each of these estimates were both listed as 1.

7. Manufacturer Identification. The minimum guidance option has the same information requirement as section I.A. of the reproposed form (Table 1). The submitter must supply the organization's name; the name and address of: (1) the technical contact, (2)parent organization, and (3) the person filing the notice, and the intended date of manufacture for commercial purposes.

ADL estimated the technical hours for this requirement to be zero and the managerial hours to be 1-8. Since the managerial hours were provided for this requirement, the fraction for managerial hours was set at 1. No fraction needed to be estimated for technical hours, since any fraction of zero is zero.

8. Health and Environmental Data. The minimum guidance option required the same information on health and environmental data that was requested in the reproposal (from Exhibit AII-2):

- Risk Assessment
- Detection Methods
- Occupational Exposure (previously counted under the byproducts and occupational exposure requirements)
- Environmental Release and Disposal (previously counted under the method of disposal requirement)
- Consumer and Commercial User Exposure (subsections II.C.1 and II.C.4 previously counted under the use categories and by-products requirements respectively)
- Physical and Chemical Properties Data
- Health and Environmental Effects Data
- *Federal Register* Notice (previously counted under the *Federal Register* Notice requirement).

In estimating technical and managerial hours, only sections and subsections not previously counted in different requirements were considered as part of the health and environmental data requirement. (See Exhibit AII-2.) ADL provided estimates of the technical hours for each section and subsection included in the requirement. Therefore, each fraction of the technical hours was set at 1. The same was true for managerial hours except for subsections related to consumer and commercial user exposure. Therefore, the fractions of managerial hours were all set at 1 except for these subsections (II.C.2., II.C.3.). As previously stated, each subsection of section II.C. was determined to require approximately the same number of managerial hours. Because the health and environmental data requirement included two out of four such subsections, the managerial hours for the combination of these subsections was estimated to be 0.5 of the managerial hours for the entire section II.C.

Summary: Through the process described above, the total technical and managerial hours needed for providing information under the minimum guidance option were estimated to be 22.6-215.4 and 7.5-35.0, respectively. (See Exhibit AII-2.) A more simplified process was used to estimate clerical hours. This is presented below.

C. ESTIMATION OF CLERICAL HOURS

Ratios of clerical to technical hours and of clerical to managerial hours were estimated from ADL's time estimates for the reproposed form. These time estimates, by labor category, were as follows:[7]

Clerical	8-40 hours
Technical	27-267 hours
Managerial	8-37 hours

Using the lower hours estimates, we created the first column of Exhibit AII-3. Using the higher hours estimates, we created the second column of the exhibit.

Exhibit AII-3

Ratios of Clerical to Technical Hours and of Clerical to Managerial Hours

Ratio	Ratio of Minimum Hours	Ratio of Maximum Hours
Clerical Hours to Technical Hours	.296	.150
Clerical Hours to Managerial Hours	1.000	1.080

Clerical hour estimates for the minimum guidance options were obtained by multiplying these ratios by the estimated total technical and managerial hours needed to provide information under the option. Once estimates of the clerical hours were obtained in this fashion, averages were taken to obtain a single range for the number of clerical hours required (refer to Exhibit AII-4). The estimated range was 7.1-35.1 hours.

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[7] Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, p. 38.

Exhibit AII-4
Estimated Clerical Hours

Ratio	Minimum Hours	Maximum Hours
Based on Clerical to Technical Hours Ratio	6.69	32.30
Based on Clerical to Managerial Hours Ratio	7.50	37.80
Approximate Average	7.10	35.05

D. ESTIMATION OF THE TOTAL COST OF COMPLETING THE MINIMUM GUIDANCE OPTION

To estimate the total cost of completing a notice under the minimum guidance option, average hourly wage rates by labor category were multiplied by the respective number of hours needed to complete the notice. The average hourly wages were the same as those established by ADL: $10/hour clerical, $25/hour technical, and $50/hour managerial. The results are presented in Exhibit AII-5.

Exhibit AII-5

Cost of Completing Minimum Guidance Option

Labor Category	Estimated Hours to Complete Alternative 1 Notice		Average Wage Rate	Estimated Cost of Completing Alternative 1 Notice	
	Minimum	Maximum		Minimum	Maximum
Clerical	7.1	35.1	$10	$ 71	$ 351
Technical	22.6	215.4	$25	$565	$5385
Managerial	7.5	35.0	$50	$375	$1750
			Total Cost	$1011 to	$7486

Thus, the total cost of submitting a notice under the minimum guidance option ranged from approximately $1,000 - $7,500.

III. USE OF ADL METHODOLOGY TO ESTIMATE THE COST OF THE OCTOBER 1979 NOTICE REQUIREMENT FOR IMPORTERS

ADL estimated the cost of completing each section of the October 1979 notice form for domestic manufacturers. Using these section-by-section estimates, the cost of completing the October 1979 notice for Importers can be easily estimated. This is done through the following procedure:

- List each section of the Importer notice
- Beside each of these sections, list the section of the notice form for domestic manufacturers that requests roughly the same information. (This section of the domestic manufacturers' notice form is termed a "comparable section.")
- Record ADL's estimated ranges of clerical, technical and managerial labor hours for each comparable section.
- Sum the minimum clerical hours across all comparable sections and then the maximum clerical hours. Do the same for technical and managerial hours.
- Multiply the minimum clerical hours by ADL's prescribed wage rate for clerical labor, do the same for the minimum technical and managerial hours, and sum these products to obtain a minimum total cost.
- Repeat the above step for maximum hours to obtain a maximum cost. The minimum and maximum costs comprise the estimated cost range of completing the October 1979 notice for importers.

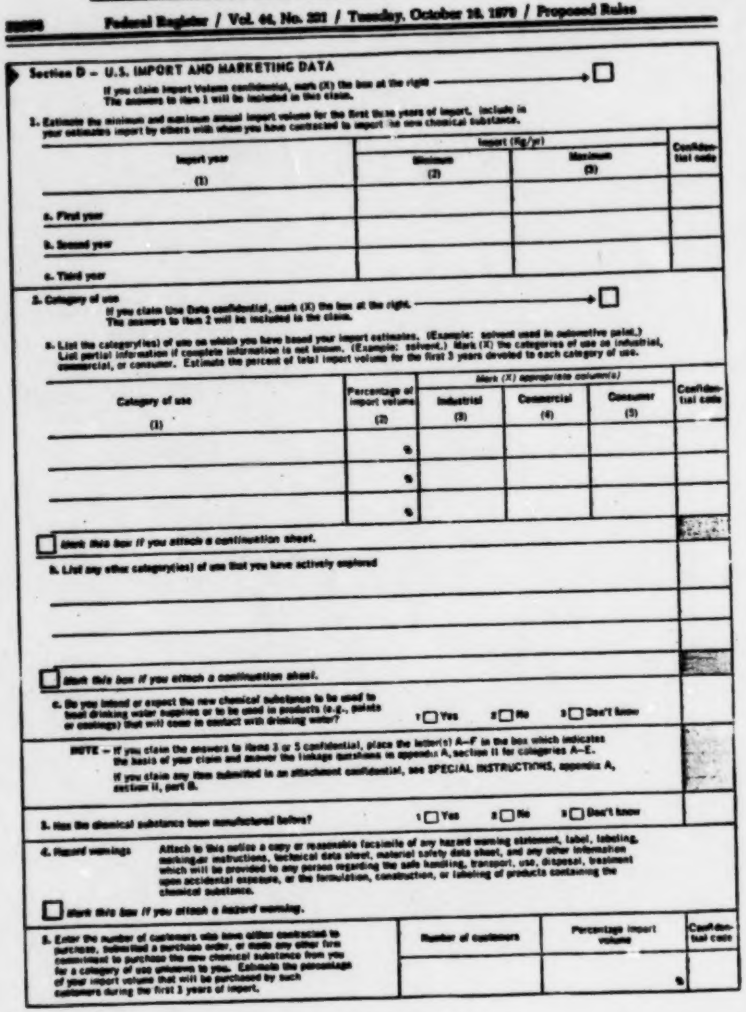
The above procedure cannot be done if a section of the importer notice does not have a comparable section of the notice form for domestic manufacturers. Fortunately, this is not the case. In fact, importer sections are quite similar to domestic manufacturer sections in terms of required information. Exhibit AIII-1 displays an example of the similarity between comparable sections of both forms.

The comparable sections that appear to be the most dissimilar are the sections of both forms dealing with transport. This is understandable, as it is transport that distinguishes domestic manufacturers from importers. However, the only difference between the sections is that the importer section has an extra multiple-choice question on the mode(s) of transport into the United States. It is estimated that this extra question requires a negligible amount of labor relative to the section's other labor requirements. Therefore, the manufacturer's transport section appears to serve as a good

EXHIBIT AIII-1

EXAMPLE OF SIMILARITY BETWEEN COMPARABLE SECTIONS

Importer Notice Section



[illegible] Federal Register / Vol. 44, No. 201 / Tuesday, October 16, 1979 / Proposed Rules

Section D – U.S. IMPORT AND MARKETING DATA

If you claim Import Volume confidential, mark (X) the box at the right → ☐
The answers to item 1 will be included in this claim.

1. Estimate the minimum and maximum annual import volume for the first three years of import. Include in your estimates import by others with whom you have contracted to import the new chemical substance.

Import year (1)	Import (Kg/yr) Minimum (2)	Import (Kg/yr) Maximum (3)	Confidential code
a. First year			
b. Second year			
c. Third year			

2. Category of use
If you claim Use Data confidential, mark (X) the box at the right. → ☐
The answers to item 2 will be included in the claim.

a. List the category(ies) of use on which you have based your import estimates. (Example: solvent used in automotive paint.) List partial information if complete information is not known. (Example: solvent.) Mark (X) the categories of use as industrial, commercial, or consumer. Estimate the percent of total import volume for the first 3 years devoted to each category of use.

		Mark (X) appropriate column(s)			
Category of use (1)	Percentage of import volume (2)	Industrial (3)	Commercial (4)	Consumer (5)	Confidential code
	%				
	%				
	%				

☐ Mark this box if you attach a continuation sheet.

b. List any other category(ies) of use that you have actively explored

☐ Mark this box if you attach a continuation sheet.

c. Do you intend or expect the new chemical substance to be used to treat drinking water supplies or to be used in products (e.g., paints or coatings) that will come in contact with drinking water? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know

NOTE – If you claim the answers to items 3 or 5 confidential, place the letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A–E.

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

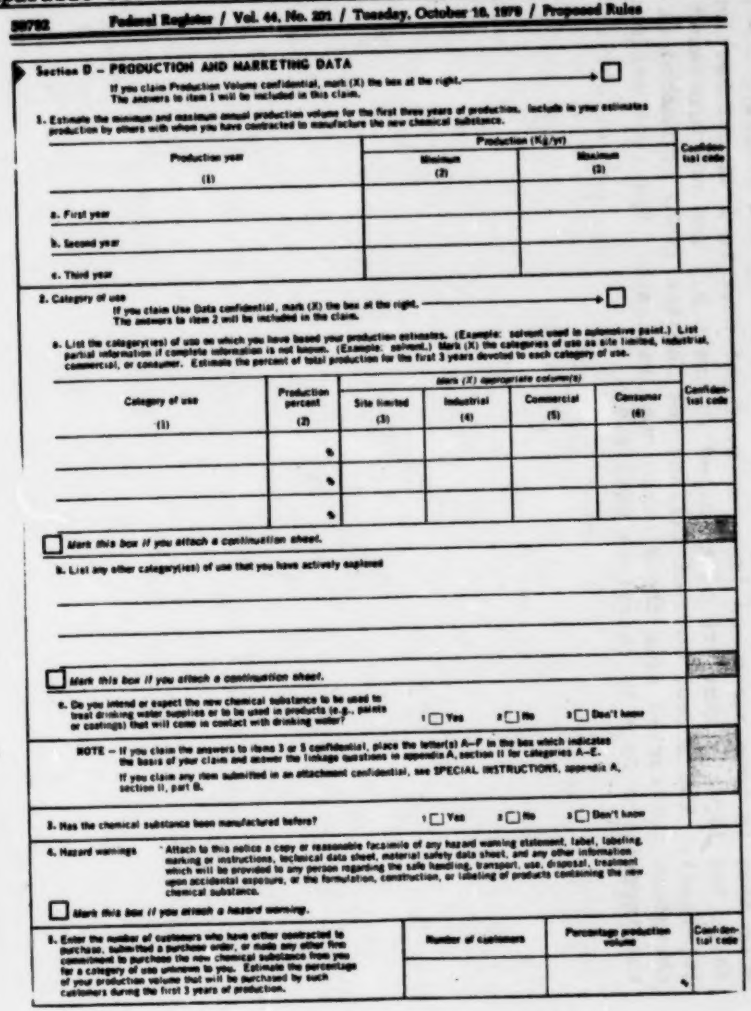
3. Has the chemical substance been manufactured before? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know

4. Hazard warnings — Attach to this notice a copy or reasonable facsimile of any hazard warning statement, label, labeling, markingor instructions, technical data sheet, material safety data sheet, and any other information which will be provided to any person regarding the safe handling, transport, use, disposal, treatment upon accidental exposure, or the formulation, construction, or labeling of products containing the chemical substance.

☐ Mark this box if you attach a hazard warning.

5. Enter the number of customers who have either contracted to purchase, submitted a purchase order, or made any other firm commitment to purchase the new chemical substance from you for a category of use unknown to you. Estimate the percentage of your import volume that will be purchased by such customers during the first 3 years of import.	Number of customers	Percentage import volume	Confidential code
		%	

Comparable Section of Notice Form for Domestic Manufacturers



[illegible] Federal Register / Vol. 44, No. 201 / Tuesday, October 16, 1979 / Proposed Rules

Section D – PRODUCTION AND MARKETING DATA

If you claim Production Volume confidential, mark (X) the box at the right. → ☐
The answers to item 1 will be included in this claim.

1. Estimate the minimum and maximum annual production volume for the first three years of production. Include in your estimates production by others with whom you have contracted to manufacture the new chemical substance.

Production year (1)	Production (Kg/yr) Minimum (2)	Production (Kg/yr) Maximum (3)	Confidential code
a. First year			
b. Second year			
c. Third year			

2. Category of use
If you claim Use Data confidential, mark (X) the box at the right. → ☐
The answers to item 2 will be included in the claim.

a. List the category(ies) of use on which you have based your production estimates. (Example: solvent used in automotive paint.) List partial information if complete information is not known. (Example: solvent.) Mark (X) the categories of use as site limited, industrial, commercial, or consumer. Estimate the percent of total production for the first 3 years devoted to each category of use.

		Mark (X) appropriate column(s)				
Category of use (1)	Production percent (2)	Site limited (3)	Industrial (4)	Commercial (5)	Consumer (6)	Confidential code
	%					
	%					
	%					

☐ Mark this box if you attach a continuation sheet.

b. List any other category(ies) of use that you have actively explored

☐ Mark this box if you attach a continuation sheet.

c. Do you intend or expect the new chemical substance to be used to treat drinking water supplies or to be used in products (e.g., paints or coatings) that will come in contact with drinking water? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know

NOTE – If you claim the answers to items 3 or 5 confidential, place the letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A–E.

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

3. Has the chemical substance been manufactured before? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know

4. Hazard warnings — Attach to this notice a copy or reasonable facsimile of any hazard warning statement, label, labeling, marking or instructions, technical data sheet, material safety data sheet, and any other information which will be provided to any person regarding the safe handling, transport, use, disposal, treatment upon accidental exposure, or the formulation, construction, or labeling of products containing the new chemical substance.

☐ Mark this box if you attach a hazard warning.

5. Enter the number of customers who have either contracted to purchase, submitted a purchase order, or made any other firm commitment to purchase the new chemical substance from you for a category of use unknown to you. Estimate the percentage of your production volume that will be purchased by such customers during the first 3 years of production.	Number of customers	Percentage production volume	Confidential code
		%	

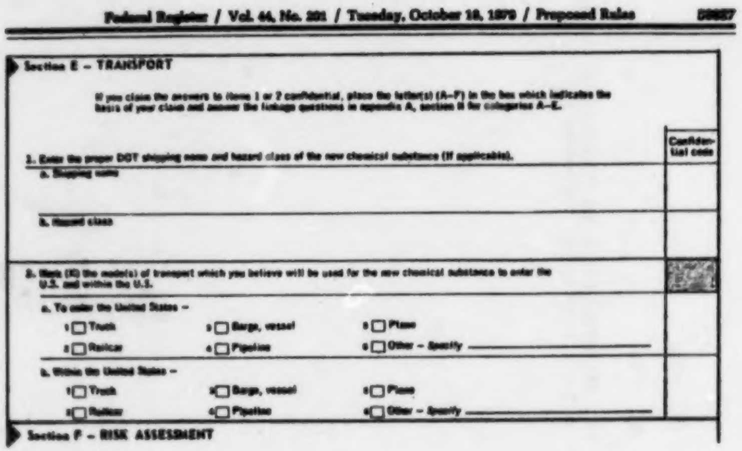
basis for the labor estimates of the importer section. Both sections are presented in Exhibit AIII-2.

Exhibit AIII-3 outlines the costing methodology and displays the results. Note that in some cases, an importer will not have to fill out Section II-A (e.g. for imports that are distributed in the U.S., and not processed by the importer). The lowest cost of filling out Section II-A, estimated at $300, is therefore subtracted from the minimum cost estimate. The cost estimate for the importer's form is therefore $855-$8925.

EXHIBIT AIII-2

IMPORTER AND DOMESTIC MANUFACTURER NOTICE REQUIREMENTS ON TRANSPORT

Importer Section



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Section E – TRANSPORT

If you claim the answers to items 1 or 2 confidential, place the letter(s) (A–F) in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A–E.

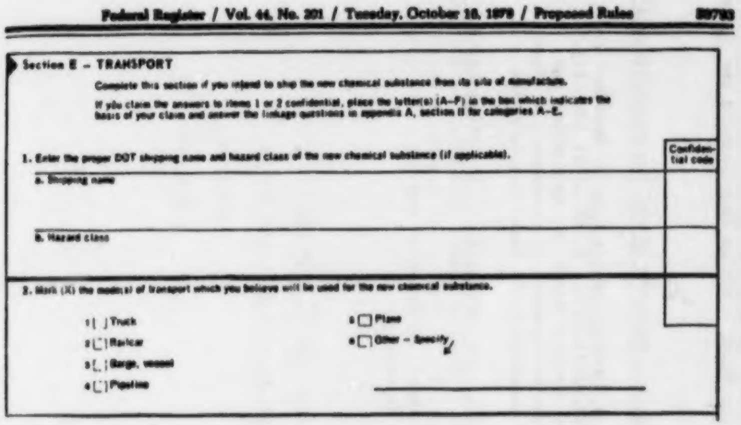
Confidential code

1. Enter the proper DOT shipping name and hazard class of the new chemical substance (if applicable).
   a. Shipping name
   b. Hazard class

2. Mark (X) the mode(s) of transport which you believe will be used for the new chemical substance to enter the U.S. and within the U.S.
   a. To enter the United States –
      1 ☐ Truck 3 ☐ Barge, vessel 5 ☐ Plane
      2 ☐ Railcar 4 ☐ Pipeline 6 ☐ Other – Specify ______
   b. Within the United States –
      1 ☐ Truck 3 ☐ Barge, vessel 5 ☐ Plane
      2 ☐ Railcar 4 ☐ Pipeline 6 ☐ Other – Specify ______

Section F – RISK ASSESSMENT

Comparable Section of Notice Form for Domestic Manufacturers



Federal Register / Vol. 44, No. 201 / Tuesday, October 16, 1979 / Proposed Rules 59793

Section E – TRANSPORT

Complete this section if you intend to ship the new chemical substance from the site of manufacture.

If you claim the answers to items 1 or 2 confidential, place the letter(s) (A–F) in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A–E.

Confidential code

1. Enter the proper DOT shipping name and hazard class of the new chemical substance (if applicable).
   a. Shipping name
   b. Hazard class

2. Mark (X) the mode(s) of transport which you believe will be used for the new chemical substance.
   1 ☐ Truck 5 ☐ Plane
   2 ☐ Railcar 6 ☐ Other – Specify
   3 ☐ Barge, vessel
   4 ☐ Pipeline ______

Exhibit AIII-3
Estimated Cost of Completing October Notice for Importers, Based on ADL Estimates for October Notice Requirements for Domestic Manufacturers

Sections of PMN for Importers[a]	Comparable Sections of PMN for Manufacturers[b]	Estimated Hours of Importer PMN[c] Clerical	Technical	Managerial
I. General Information, A. Importer Identification, B. Chemical Identity, C. Generic Names, D. U.S. Import and Marketing Data, E. Transport, F. Risk Assessment, G. Detection Methods.	I. General Information, A. Manufacturer Identification, B. Chemical Identity, C. Generic Names, D. Production and Marketing Data, E. Transport, F. Risk Assessment, G. Detection Methods.	2-10	7-59	2-13
II. Human Exposure and Environmental Release, A. U.S. Industrial Sites Controlled by the Submitter, (may not be applicable to all importers) B. U.S. Industrial Sites Controlled by Others C. U.S Consumer and Commercial User Exposure.	II. Human Exposure and Environmental Release A. Industrial Sites Controlled by the Submitter, B. Industrial Sites Controlled by Others, C. Consumer and Commercial User Exposure.	4-20	7-144	2-10
III. List of Attachments	III. List of Attachments	1-8	12-56	3-12
IV. Federal Register Notice	IV. Federal Register Notice	1-2	1-8	1-2
	Total Hours	8-40	27-267	8-37
	X Cost/Hour	X 10	X 25	X 50

Minimum Total Cost	Maximum Total Cost
$1,155	$8,925

Note: Because importers may not always submit Section II-A (estimated to cost $300-$2100), the minimum total cost is reduced by $300.

Cost Range: $855-$8925

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[a] 44 Federal Register 59852-59866, October 16, 1979.

[b] 44 Federal Register 59788-59802, October 16, 1979.

[c] Estimates taken from Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, prepared for the EPA Office of Toxic Substances, September 1979.

APPENDIX B

ASSESSMENT OF THE FEASIBILITY OF DEVELOPING A METHODOLOGICAL FRAMEWORK FOR FORMAL ECONOMIC IMPACT ANALYSIS

ASSESSMENT OF THE FEASIBILITY OF DEVELOPING A METHODOLOGICAL FRAMEWORK FOR FORMAL ECONOMIC IMPACT ANALYSIS

This report presents the results of a brief (two-month) small-scale review undertaken by ICF Incorporated to assess the technical feasibility of developing a formal economic approach to analyze the impact of TSCA's Section 5 notice requirements on the U.S. chemical industry. In conducting this review, ICF began with, and drew heavily upon, a preliminary working paper by Arthur D. Little, Incorporated. The ICF review was primarily directed toward two interrelated goals:

(1) Assessing the technical feasibility of a formal analytical approach to understanding the impacts of notice requirements on the chemical industry--an approach that could be used in the notice requirement economic analysis to be completed within six months or so.

(2) Learning from the existing literature on innovation the significant probable factors affecting chemical industry innovation so that later tasks of the project could be focused upon these factors.

A secondary goal of the task was to comment upon the analytical approaches proposed in the working paper, approaches which have a longer-term and broader objective than the notice requirement analysis: the construction of an analytical tool or model of the U.S. chemical industry which could be used to examine *ex ante* effets of a wide variety of TSCA reguations.

This report is organized as follows:

SUMMARY OF FINDINGS--summarizes the conclusions of the report in response to five specific questions asked by EPA in its work statement.

INTRODUCTION--defines the objective of the study and discusses briefly the reasons for the emphasis of the following sections.

LITERATURE REVIEW--briefly summarizes the relevant literature.

FORMAL ANALYTIC APPROACHES--outlines the alternative approaches for formal analytical modeling and discusses their data requirements, benefits, shortcomings, and costs.

BIBLIOGRAPHY of relevant sources.

SUMMARY OF FINDINGS

This section summarizes the findings of this report in response to the specific questions asked by EPA in Task Order 3 of November 10, 1979.

(1) We have argued against the formal analytic approaches recommended by ADL (econometric models) because, most importantly, there is no apparent way to use the tools suggested to test the effects of TSCA regulation on chemical industry product innovation, the key issue not only for notice requirement effects but probably for TSCA as a whole.

(2) We have reviewed the generally thorough ADL literature search and other literature and summarized its utility. It provides some indication of probable factors affecting chemical industry innovation, but is not very useful in providing either theory, methods, or data to support formal analytical approaches.

(3) We have concluded that neither the ADL approaches to formal analysis nor the ICF alternative can be completed in time to study notice requirement impacts.

(4) We have produced a conceptual model of the chemical innovation process and outlined the data and relationships necessary to understand it better, as an input to the notice requirement economic impact analysis task.

(5) We have summarized for EPA the longer-run feasibility of formal technical approaches and reached the following conclusions:

(a) The best hope for a model of product innovation is a simulation approach which relies upon simulating the R&D resource allocation decision and commercialization decision, based upon risk, cost, expected payoffs, and timing of these factors. TSCA regulatory impacts would be assessed through changing the costs, timing, and probabilities of payoffs.

(b) If the product innovation decision can be modeled (see below), there are a variety of interesting ways to trace economic impacts through industry simulation or optimization models. We recommend deferring these interesting questions until the feasibility of (a) is tested.

(c) The best approach to test the feasibility of (a) is to run a small-scale pilot on one industry segment with high product R&D. This will require original data collection from industry, take about nine months, and cost about $100,000. It is by no means certain it will result in a useful model (although it would necessarily shed some light on the R&D practices in that segment).

(d) If (c) is tested and fails, EPA could at a later date consider formal industry models of the kind proposed either by ADL or ICF. Such a project, realistically, is a three to five year (over $1 million) effort, and, although it would be a useful tool for many purposes, could not be effectively used to assess ex ante the economic impacts of TSCA regulations on innovation.

(e) If (c) is tested and succeeds, EPA could begin to build the larger chemical industry model block by block, with the first work being to construct the model of the industry segment for which (c) was built and, then integrate the models.

INTRODUCTION

Objectives

The objective of this task is to assess the technical feasibility of developing a formal economic approach to analyze the impacts of notice requirements (and by implication those of other TSCA regulations) on the U.S. chemical industry. As will become clear below, it is extremely important to understand the ramifications of this objective:

- The notice requirements to be modeled apply to new chemical products, which inevitably turns the focus of the study to new product development: the innovation or research and development process in the chemical industry.

- As amplified below in the literature summary, there is very little in the literature which can help with this task.

- Because of the sophisticated tools available for industry econometric modeling (and through input-output analysis for tying industry effects to overall economic effects), there is a strong tendency to propose the construction of a large chemical industry econometric model. Without doubt, some industry model is necessary to track the impacts of innovation effects and change once these impacts are understood. But, unless the innovation process can be understood well enough to model so that the impacts of regulation upon it can be understood, it is of no use to have a sophisticated means to track the effects of these impacts. Note that although a partial or general equilibrium econometric model would have some use for TSCA for issues other than notice requirements, it is our view that TSCA effects on innovation will be such a fundamental point of contention about impacts that any large modeling effort must address innovation.

- There are considerable dangers in over-aggregation. It is by no means clear that there is a "chemical industry" in the sense of, say, coal or pharmaceuticals, but instead perhaps a set of "industries," with little in common, that must be addressed separately for many analytical purposes. For example, the "Perfumes, Cosmetics, and other Toilet Preparations" industry segment (SIC 2844) may have less in common with, say, "Explosives" (SIC 2892) than the steel industry has with, say, aluminum.

Brief Summary of Literature

Because the organization and conclusions of this report depend directly upon the findings from the literature search, we have highlighted these findings in this section. There are four primary bodies of literature of possible relevance:

(1) The formal microeconomic literature on industrial innovation. Neoclassical growth theory has struggled for many years to deal with technological change. In the 1960s economists developed a means of incorporating technical change in the neoclassical growth model as the "theory of induced innovation"--but in a very formal manner which is of little use in the current task. This is because, first, the theory deals with what we would call "process innovation"--changes in the prices and quantities of input factors for given outputs.[2] New product development falls completely outside these theories.

Next, the theory has been developed largely at a macroeconomic level. Finally, there seems to be little theory in the economics literature on the role of uncertainty in the innovation process--either at the firm level, industry level, or macroeconomic level. It is possible to distinguish between "technical uncertainty" (the uncertainty that the scientific and engineering development process will produce something of potential use) and "market uncertainty" (the uncertainty about the degree of demand for a product in the future and about how actions of competitors may affect payoffs). It is also theoretically possible to model "technical uncertainty" through a probability cash flow model, "market uncertainty" through a game-theoretic approach, and the two together through incorporation into a portfolio-choice capital budgeting model for R&D expenditures. But there is almost no body of microeconomic theory to rely upon, unlike other areas of industry and firm behavior.

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[2] Even here, there is much confusion and apparently no clear way empirically to separate movement along an isoquant (factor substitution) and shifts in the isoquant (technical change). Because of the difficulty in separating the two (in either case, the optimal factor ratio changes in favor of more use of the less expensive factor), several economists have recommended abandoning the distinction entirely.

Although economists are now moving into this field to close the gaps mentioned, it is worth repeating what is to us a surprising finding: there is at present very little economic literature or theory on product innovation. On the one hand, this makes the problem doubly interesting from an academic viewpoint (and because of this EPA should maintain a clear focus on new advances in model-building); on the other hand, economic modeling of product innovation (quite apart from the even more difficult issue of TSCA impact on that innovation) puts us at a frontier of economic theory without tested or accepted approaches upon which to rely.

(2) Empirical studies of innovation. There are extensive studies, generally at the industry level, which attempt to analyze and understand the industrial research and development process. These range from studies which are quite analytical and use formal models and actual historical data (usually time-series or pooled time-series/cross sectional multiple regression analysis) to qualitative case studies. Industries covered are primarily drugs, chemicals, glass, steel, or petroleum. Attempts are made to relate the amount of R&D expenditures to a wide variety of firm and industry parameters and to relate "outputs" such as sales of new products to amounts of R&D expenditures. Despite the recent work of Mansfield, Nelson, Iverstine, and others, there is not much empirical detail on the resource allocations to the various stages of the R&D process, on how and why firms make R&D allocation decisions, on how firms evaluate R&D expenditures, or on how firms (in a game-theoretic sense) decide what to patent or bring to market. As discussed below (and in the ADL survey), this literature provides some ideas about the determinants and decision-making in the R&D process, but the bulk of it is not very useful for several reasons:

- It is based upon old data (often, say, 1954-1959) and thus upon structural and societal relationships and forces which arguably no longer pertain.

- It is conflicting in many of its findings.

- It is often based upon questionable data and surrogates for innovation (due to lack of useful data) and at rather high levels of aggregation (i.e., even at the large company level, there are many very different "businesses" being aggregated).

- There are few studies of the chemical industry and few significant conclusions from these studies.

(3) Specific studies on the effects of government regulation on innovation. There has been reasonably extensive study of the impacts of the 1962 Amendments to the Food, Drug and Cosmetic Act on innovation in the pharmaceutical industry and to a lesser degree on the effects of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) on the pesticides innovation process. As discussed below, although these studies highlight some areas of interest to TSCA, they are of little use here. Either:

- the studies are generally post hoc analyses with single equation approaches or international comparisons, neither of which is particularly helpful to TSCA's objective of developing an approach to assess impacts ex ante;
- the studies deal with regulations very different from notice requirements (and different from TSCA more generally); or
- the studies are data constrained, in some cases use questionable surrogates for innovation, fail to separate the regulations themselves from concurrent societal forces, and provide little data on how regulations have affected R&D decision-making by firms.

(4) Studies from the "business literature". There is a growing literature on R&D, innovation, and technical change arising from managerial sources, which provides some useful empirical insights. The literature ranges from studies of R&D strategy to the extensive work done on capital budgeting, decision-making under uncertainty (particularly Bayesian statistics), and portfolio/risk theory. Although these are useful grounds upon which to model certain business decision-making, much of this literature is too abstract and complex to be applied to the variety of common business decisions: there remains a significant gap between the case studies of individual firms and a formal analysis of a business decision under uncertainty. Yet, in view of the necessity to understand the effects of notice requirements on the chemical industry and of the limited usefulness of the literature cited above in (1), (2), and (3), it is apparent that how and why chemical industry decision-makers allocate R&D resources, assess probabilities, and make decisions about development and commercialization is the critical first factor which must be understood or modeled if we wish to know how notice requirements may affect this process.

LITERATURE REVIEW

We noted in the introduction that the existing literature has little to offer in developing a formal approach to analyze the impacts of notice requirements on the chemical industry. In this section a brief summary of the literature is provided. Numbered citations in the text refer to the bibliography at the end of this appendix.

There are four areas of the literature:

- microeconomic theory of industrial innovation;
- empirical studies of innovation;
- specific studies of the effects of government regulation on innovation; and
- "business" literature.

Microeconomic Theory of Industrial Innovation

In this category, the review by ADL is more than adequate; therefore, the conclusions documented in the ADL report are summarized and restated:

- The theory of induced innovation that is incorporated into neoclassical growth models addresses only process innovation.
- Research and development costs are seldom even included in models; when they are, there are serious difficulties. Economists do not agree whether the firm has a choice in the direction of technical innovation; some believe that to admit that firms can control the rate or direction of technical change requires abandoning competitive models.
- Most past efforts have been in a macroeconomic framework.
- Existing models do not deal either with technical uncertainty or market uncertainty, or with how allocation decisions would (or should) change with changes in these factors. TSCA regulation is expected to affect both technical uncertainty (by increasing the number of technical criteria a product must respond to) and market uncertainty (by adding costs, increasing delays, weakening competitive position, reducing payoffs, etc.); there is no systematic means to deal with regulatory effects in these models.

Empirical Studies of Innovation

In this category, the ADL review was also thorough. Conclusions in these studies are often contradictory; for example, on how diversification affects innovative activity: Grabowski finds a positive effect, Scherer finds no systematic effect, and Weiss finds a negative effect. Even when there are findings--e.g., that R&D intensity (as measured by R&D employment regressed against sales) tends to rise with firm size in the chemical industry--there are no straightforward implications for the task at hand.

In broad summary, here are some findings from this literature:

- At the firm, industry, and economy level, there is high correlation between R&D expense and economic growth/ productivity. The ADL report cites R&D intensity as a "source" of growth (although noting that causality may run in both directions); more conservatively stated, high R&D is associated with high growth and positive changes in productivity.
- Chemical industry R&D intensity appears to rise with firm size, yet R&D per sales dollar is higher with smaller firms.
- There is no consensus on the relationship between innovative activity and industry concentration or degree of product differentiation.
- Several studies suggest after-tax average returns on R&D capital of 15 to 20 percent.
- One expert (Kamien) estimated that more than three-fourths of U.S. industrial R&D was directed toward new products rather than new processes.

Specific Studies of the Effects of Government Regulation on Innovation

ICF looked closely at the previous work in the pharmaceutical and pesticides industries because, despite its *ex post* nature and regulatory differences from TSCA, the general approach used at least addressed directly the relationship between regulation and innovation. Thus, the following section provides a little more detail than the previous two summary sections; without doubt, TSCA will be subject to analyses similar to these in the future.

This summary of the literature is a brief guide to what is known about the effects of regulation on innovation in the pesticide and pharmaceutical industries and how it may relate to the chemical industry. References are made to major empirical studies in the bibliography.

The Pharmaceutical Industry.

A number of studies have been done on the effects of the 1962 Amendments to the Food, Drug and Cosmetic Act on innovation and R&D in the pharmaceutical industry. The most significant findings are summarized here in terms of the following four hypothesized impacts of regulation on innovation. Regulation:

(1) lowers return on R&D due to increased costs, risk, and development time associated with regulatory compliance, leading to a lowered rate of investment in R&D and potential decline in innovation;

(2) changes the pattern of R&D and innovation (e.g., away from basic research to emulative products or from product to process innovation);

(3) changes market structure which may affect the rate and pattern of innovation; and

(4) promotes international transfer of resources and technology from countries with strict regulatory requirements to those with less strict requirements.

1. Level of Innovation. Based on Baily's study (7) showing an increase in new drug discoveries resulting from increased R&D expenditures, several authors have investigated the expected rate of return on pharmaceutical R&D investment (19, 82). Schwartzman, for example, finds a drop in the rate of return from 11.4 percent in 1960 to 3.3 percent in 1972 due to increased costs posed by government regulation.

Hansen (38) estimates a development cost of $54 million (1976 dollars) for a new chemical entity (NCE) and about nine years for the NCE to reach the market. Many others have documented the decline in introduction of NCE's since 1962. (See 43, 55, 74, 90, 91.) The exact portion of that decline directly attributable to regulation is, however, still open to question.

Both Baily (7) and Peltzman (74) find a statistically significant negative effect of regulation on the number of new chemical entities introduced in the U.S. after 1962, but serious criticisms of these empirical models exist. For example, Baily's supply-side model ignores the effects of changes in demand, and both Baily and Peltzman neglect to provide an adequate measure of "research depletion" or to explore the possibility that any exhaustion of research opportunities actually existed.

Using a comparative analysis of the British and American cases to get at the same issue, Grabowski, Vernon, and Thomas (32) find a six-fold decline in R&D productivity in the U.S. between 1960-1961 and 1966-70, compared to a three-fold decline in the U.K. in the same time period. The difference between the two countries may be part of the well-known "drug lag", suggesting that it was the particular legal and institutional form of regulation in the United States that has been most responsible for negative effects on innovation.

As for the three-fold decline in the U.K. rate, it is again not possible to distinguish the effects of increased regulation in that country from research depletion or from changes in demand due to a different social and medical context.

The Arthur D. Little paper (4) emphasizes the importance of a simultaneous equation approach to modeling innovation in the drug industry, rather than single-equation models which model either the supply side or the demand side, but not both together. The 1962 legislation in the U.S. (and regulation in other countries) was one aspect of a change in attitudes directly related to the thalidomide incident which arguably affected demand for new drugs. On the supply side, the possibility of exhaustion of research opportunities, perhaps due to gaps in scientific knowledge, is an important and controversial issue that has not been effectively addressed in econometric studies of this subject.

2. Type of Innovation. The position taken by the FDA is that the decline in new drugs since 1962 has been a result of the focus on new chemical modifications of existing drugs, rather than the inhibition of new therapeutic advances. This position is a controversial one both factually and in its tacit assumption that society has not lost much from the decline in slightly modified drug products. The nature of new drug innovation is dealt with in several sources (see 39, 74, and 81).

3. Market Structure. A great deal of literature has dealt with questions of market structure and innovation in the pharmaceutical and several other industries. Most writers have explored the relationship of firm size to innovation in an attempt to empirically assess Schumpeter's hypothesis that large firms are associated with greater inventive output (80). (See, for example, 5, 12, 24, 35, 37, 59, 78, 81, and 88.) It appears that there is still little consensus on the validity of this hypothesis.

Kamien and Schwartz (46) provide a useful survey of research done on this question, noting the two aspects of the "scale" issue: the effect of firm size on efficiency for a given size R&D facility, and the efficiency of different sized R&D facilities within a firm. More recent studies have investigated the effects of rivalry on the innovation process (31, 47, 66).

As in the pesticide industry, active ingredient R&D on pharmaceuticals is conducted by a limited number of firms (approximately 100) and is generally confined to the larger companies because of high development and testing costs.

4. International Transfer. A fair amount of evidence has been amassed indicating that there has been a geographical shift from the U.S. to overseas in the location of pharmaceutical innovation since 1962 as a result of differential regulatory requirements. The pharmaceutical industry has a strong multinational component, so that a shift in R&D and production can be effected with some ease. It is difficult, however, to separate out the effects of regulation from other cost-related factors on this trend. (See 32 and 33.)

The Pesticide Industry. Very little literature exists on the effects of regulation on innovation in the pesticide industry. The primary sources of data are the industry surveys carried out by the National Agricultural Chemicals Association (69). These surveys, however, vary from year to year in the number of firms participating and the categories used, so that a detailed analysis of trends in innovation is not always possible. Some idea of recent patterns in the industry can, however, be gleaned from the NACA data and other sources.

Expenditures on pesticide research and development have continued to rise in the last decade, keeping pace with the increase in pesticide sales. The cost of bringing a new chemical to the market, though, has risen from estimates of $5.5 to $6 million in the early 1970s to a current estimate of $15 to $20 million (including the cost of unsuccessful compounds). Total elapsed time from discovery of a pesticide to marketing has also been increasing, from an average of 60 months in 1967 to 110 months in 1977. Although the share of R&D funds spent on discovery and commercialization of new products has been roughly constant in the last five years (near 65 percent), a much higher proportion of R&D expenditures is now devoted to regulation-related activities. The result is that fewer new commercial products have been forthcoming, and it is assumed that the number of annual new registrations of active ingredients with EPA will not exceed 10 to 15 in the near future.

Unfortunately, no precise linkage of the changes in pesticide innovation with the effects of FIFRA regulation is possible. The pesticide industry is relatively mature (70) and it is generally believed that most major markets have already been filled with effective products, though product obsolescence is common in the industry. On the other hand, registration requirements have probably exacerbated the trend toward increasing modification of existing pesticides for new uses rather than developing new chemical entities.

There is, in addition, a wide variety of anecdotal evidence that direct and indirect effects of regulation have hindered both the development of products for minor crops and uses, and innovative work in the development of biological alternatives to chemical pesticide control. It is believed that the few small firms that are involved in pesticide R&D have been involved in some of this innovative work (23). The effects of regulation on market structure, although limited, may therefore be indirectly injurious to some sources of innovation.

The Chemical Industry. The relevance of the experience of the pesticide and pharmaceutical industries under premarket regulation to the effects of TSCA on the chemical industry is severely limited. Apart from methodological problems in the formal analytical approaches contained in previous studies which limit their usefulness for studying the chemical industry, there are important substantive differences among the industries.

Pesticides and pharmaceuticals are not typical segments of the larger chemical industry. The levels of R&D conducted in the industries differ significantly, (about 10 percent of sales in pharmaceuticals, eight percent in pesticides, and two to four percent for chemicals). Although the lack of data available for the chemical industry precludes definitive statements, it is suspected that other important differences exist as well. Examples are the expected value of sales of new products, the barriers to entry into R&D, and in general, the effect of firm size and scale of R&D facility on innovative potential (see 26 and 30). Whether or not the role of small firms in chemical R&D and whether or not the research opportunities facing the chemical industry are substantially different than the pesticides and pharmaceuticals cases could also modify the effects of regulation on the industry.

Variations in the regulatory process faced by different industries may likewise be important. Premanufacture notification does not require specific testing or explicit approval, and has a maximum review period of 90 days (may be extended to 180 days) after which a chemical may be introduced into commerce. The FIFRA pesticide registration program and FDA's Investigative New Drug (IND) approval system require explicit approval after review of test results before a product can be manufactured, and the review period can extend indefinitely. Similarly, the treatment of confidential information in the regulatory process may affect not only the rate of innovation but the type of innovation (i.e., variations on existing chemicals or entirely new types of chemicals) and the location of activity.

Measurement of innovation appears in the literature on pharmaceuticals as a serious obstacle to empirical study. The problem is aggravated in the case of the chemical industry, where even the annual number of new chemical entities introduced is unavailable from a single authoritative source. Some of these issues are dealt with in (52), (66), (77), and (78), and in the final section of this appendix.

For these reasons, it is not likely that the major studies done on the pharmaceutical industry or the experience of the pesticide industry can be easily extrapolated to predict TSCA's effect on the chemical industry. No doubt some of the determinants of innovation in the industries will be common. However, it is not our expectation that the results of regulation in the chemical industry as a whole will conform to the results in two of its rather atypical sectors. For example, the nature of R&D in both pharmaceuticals and pesticides is more product-oriented than process-oriented, which is generally believed untrue for at least the high-volume segments of the chemical industry; most new products (active ingredients) in the former cases are expected to penetrate large markets and have development costs of $20-30 million over the course of 5 to 10 years.

What this points up is the heterogeneity of the chemical industry, and the need to disaggregate the various sectors it encompasses. It appears that pesticides and pharmaceuticals are at one end of the spectrum of chemical industry subgroups in terms of innovation. Other patterns of innovation and of regulatory effects on innovation are more characteristic of the chemical industry in general. A fuller discussion of the disaggregation of the industry in order to properly model the effects of TSCA on innovation is developed in the Formal Analytic Approaches section below.

The "Business" Literature

Apart from the extensive theoretical literature on capital budgeting, decision analysis under uncertainty, and portfolio risk analysis, the business literature also contains examinations of individual firms or innovations and behavioral studies relating organization and management approaches in R&D to successful outputs. Both these approaches look carefully at actual firm performance. Some major conclusions:

- The bulk of R&D projects in large chemical firms are relatively safe from a technical point of view (59).

- Expected rates of return (if successful) were about 30 percent--arguably about the same, after probability adjustments for some failures, as other capital investment (59).

- Firms devoted about nine percent of R&D funds to "basic research," 45 percent to "applied research," and 46 percent to "development" (60).

- Even for research-intensive industries like chemicals, innovations are often based upon technology or research derived from organizations other than the innovating firms (68).
- There is considerable anecdotal evidence that in significant parts of the chemical industry--especially for small firms and in the specialty chemicals area--a great deal of product innovation is closely tied to customers and the market (i.e., there may be little or no "market uncertainty").
- There has been considerable development of the product life-cycle theory which may have application in longer-term modeling of new chemical products.
- In case studies of successful new product innovations with major impacts, factors cited (49, 74) as significant (ceteris paribus) in promoting innovations are:

	Effect on Innovation
-- firm size	+
-- relative R&D spending: firm to industry	+
-- industry growth rate	+
-- stability of industry in terms of structural products	-
-- degree of involvement of R&D groups with potential users	+
-- degree of status, authority, and involvement of top R&D manager with the project	+
-- in-house initial support for the innovation on commercial grounds	+
-- relative sales effort for the new product, including publicity/advertising	+

Summary

As noted in the introduction, the existing literature serves mainly to describe what we do not know about chemical industry innovation and how to model it.

The conclusions we draw are:

- A major focus of any formal analytic approach must be to derive a model of the R&D innovation process itself to determine how notice requirements or other TSCA regulations would affect the factors which determine how R&D input allocations are made, how the proess itself actually operates, and how commercialization decisions are made--rather than treating R&D as one or more production/cost function equations in a large, econometric industry model.

- Whether building a formal model of the innovation process is worth doing, under existing data and resource constraints, is problematical.
- The chemical industry subcomponents are so different along the major dimensions which might affect the R&D process that no "general" aggregate model of innovation is likely to be useful.
- Developing a formal analytic approach, if it can be done usefully, should begin by modeling one subcomponet of the industry (say, a four-digit SIC code) and by focusing upon innovation outputs.
- Because completing the step above, if it can be done, is about a nine-month job, a formal analytical model cannot be in place in time for use in the notice requirement economic impact analysis.
- But, if the R&D/innovation area can be usefully modeled--so that changes to the process caused by TSCA can be separately identified and incorporated in such a way as to lead to output changes--EPA would probably be well-advised to begin the long complex task of modeling the industry (as discussed below).

FORMAL ANALYTIC APPROACHES

Before discussion of formal analytic alternatives, it is important to look carefully at the chemical industry R&D process at the firm level--and most particularly, at which parts of that process notice requirements (and more broadly TSCA) might affect. Thinking through the process at the most disaggregated level (one firm) and with the stages of innovation addressed individually allows us to decide which combinations and aggregations may later make analytical sense in testing TSCA impacts.

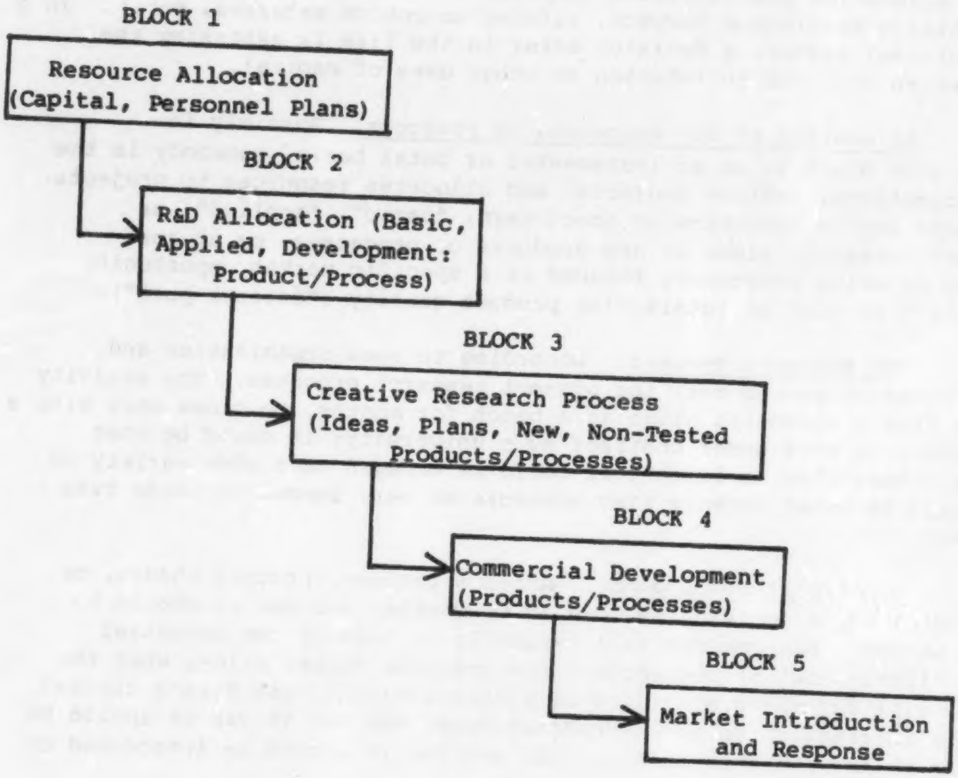
It appears evident, from the diverse literature addressing this process as a whole as well as individual elements, that each block of activity may be distinct and influenced by different factors. Further, the nature of the activity will vary widely depending upon which segment of the chemical industry is being considered and even by the individual firm within that segment. We believe it is very important to look at each block of activity and to hypothesize where notice requirements/TSCA effects might fall before any consideration of modeling.

Although we will discuss each step in the process in more detail in a following subsection on industry and microeconomic impact issues, let us summarize the activities at each step of the process:

The Innovation Process

Consider the following model of the chemical innovation process:

INNOVATION PROCESS


BLOCK 1
Resource Allocation (Capital, Personnel Plans)
BLOCK 2
R&D Allocation (Basic, Applied, Development: Product/Process)
BLOCK 3
Creative Research Process (Ideas, Plans, New, Non-Tested Products/Processes)
BLOCK 4
Commercial Development (Products/Processes)
BLOCK 5
Market Introduction and Response

Outputs

- Sales
- Profits
- Substitution

1. Allocation of R&D Inputs. The firm, through some decision-making process, decides to allocate dollars, people, office space, contract monies, and other resources to research and development. Some of these allocations may be influenced by existing R&D projects or expenditures; may be required by specific market forces; may be a result of a formal decision process or a rule-of-thumb; may be done at various levels of explicitness; and may be on an annual or project budget. But the firm has a cost of capital and alternative allocation possibilities (capital investment, marketing, dividends, hiring Washington lawyers, raising executive salaries, etc.). In a formal or informal manner, a decision maker in the firm is assessing the potential return from R&D in relation to other uses of capital.

2. Allocation of R&D Resources to Projects. Possibly in combination with Block 1, on an incremental or total basis, somebody in the firm sets objectives, defines projects, and allocates resources to projects. These projects may be long-term or short-term; "basic", "applied", or "development" research, aimed at new products or processes, or at cost reduction on existing processes; focused at a specific market opportunity ("demand-pull") or just an interesting product quality ("science-push").

3. The Research Process. According to some organization and management rules or procedures, the project research proceeds. The activity could range from a scientist alone at a bench for months, to close work with a potential user, to work under contract at a university; it could be cost engineering rather than "science"; it could be managed in a wide variety of ways; it could be under intense time pressure or very loose; it could take days or years.

4. Commercial Development. After a process, process change, or product is created, a decision is made as to whether and how it should be brought to market. Assessments will typically be made of the potential market, the likely cost of production, the possible market price, what the competition will do, the probability of success, timing, the firm's capital availability in relation to other opportunities, whether it can or should be patented (if it has not been in Block 3), and how it should be introduced or promoted.

5. Market Introduction and Response. Initially, and over what may be a very long product (or process) life cycle, the product is produced and sold. Sales may go up, cost may decrease as volumes increase, a similar but inferior product may be driven from the market, prices may rise or fall depending upon demand and competition, and a host of impacts may be traced throughout the industry and economy.

TSCA Impacts

We should note several points about TSCA's impacts on these blocks of activity. First, TSCA could have important impacts on Blocks 1 and 2 (by increasing costs and decreasing expected returns for product R&D). TSCA would impact Block 3 by potentially requiring more tests which would delay production of the new chemical and increase its cost; and by potentially causing a company to rule out certain toxic families of substances as potential products. TSCA possibly would have a major impact both on the decision process in

Block 4 (deciding what to bring to market); and on Block 5 (say, by competitors getting to market more quickly as a result of obtaining previously confidential information as a result of the notice requirements process). Alternatively, it could have almost no effect, except perhaps the cost of filing in the notice requirements form. Importantly, though, the actual decisions in Blocks 1, 2, and 4 will be made on a "marginal" basis, for that project; publicly available data is average data on expenditures and returns, and conclusions drawn from this average data about past projects are not necessarily reliable in judging future response. This point--that expectations of returns are critical in R&D decisions--is a major reason that we are pessimistic about the utility of econometric modeling. We are extremely skeptical that all R&D could be captured for an entire industry segment by one equation in a simultaneous equation model, and that even if a model could, through use of a translog cost function, derive an elasticity of demand for R&D based upon publicly available historical data, there would simply be no way to test TSCA impacts with such a model: many of the more important effects, for example, could occur on the margin and within the same R&D costs.

Thus we see the effects on these innovation process activities as being consistent with the effects measured in our economic impact analyses. New products will potentially not be introduced because TSCA may (1) increase the cost of development; and (2) introduce delays in development. For those products that do reach the marketplace, their prices will be higher (reflecting their higher cost of production) and, therefore, demand for them will be less than it otherwise would be. The extent to which these two changes (fewer new chemicals introduced, higher prices for introduced chemicals) occur will be the output of the R&D model.

Because of the need to trace industry and macroeconomic impacts of this output, it is necessary to understand how the "outputs" of an innovation model could be used to develop industry impacts before designing the innovation model. We address this issue in the next section.

Industry and Macroeconomic Impact Issues

The major problem in producing a useful policy model for TSCA is the construction of the "innovation" model described in outline form above and the integration of this model with a model of the industry and economy which can be used to determine economic impacts of changes in new product patterns. We do not plan to discuss extensively the creation of the latter model(s), because without an effective innovation model the impact model cannot be of much use to TSCA. However, several points need to be made on the issue of broader industry models, because first, we must have some idea of how the outputs of an "innovation model" would be used to assess overall industry economic pacts and, second, we have been specifically asked by EPA to comment on the ADL report and on approaches to longer-term broader modeling.

One thrust of this entire paper has been that econometric modeling (whether by simultaneous equations or otherwise) does not hold out hopes for understanding TSCA impacts on innovation, and we do not recommend any such modeling. It seems particuarly clear that a simple version of a simultaneous equation microeconometric model, built with publicly available data, is not worth doing to test notice requirement impacts. It is technically feasible, though complex, to link any of the complex interrelationships in the chemical industry in a broad partial or general equilibrium micro-econometric model. And using the "production possibility frontier" as a generalization of the production function, and corresponding cost functions is probably the best way to approach the modeling. These functions are specified mathematically in order of increasing flexibility by Cobb-Douglas, constant elasticity-of-substitution, and translog functions. The translog specification is most flexible and, although it requires a number of assumptions (e.g., competitive product markets, marginal productivity pricing), it would probably be the best framework for a micro-econometric approach.

Further, making the model a general equilibrium model through an input-output linkage is technically feasible, although there is some question whether any TSCA regulatory impacts will have great enough impacts outside the chemical industry to make such an effort useful. But it is technically possible and intellectually fascinating. To do all of the above would consume extensive resources (possibly $1 million) and take about three years. The ultimate tool could be a useful one for many EPA and other government analyses affecting the chemical industry, and it would have the benefits of thorough grounding in economic theory, flexibility, and avoiding the extensive difficulties of modeling complex process/product relationships--but it will not be able to assess the effects of TSCA reguation on chemical industry product innovation endogenously, through econometric equations, in our view.

We have outlined in the section on the innovation process, and address in somewhat more detail in the section below, a simulation model of the R&D "product innovation" process in a particular industry segment. Apart from the econometric approach discussed and dismissed above, we can see two alternative modeling frameworks for a chemical industry model to test economic impacts of changes in new product introduction profiles.

An Optimization (Linear Programming) Model. The innovation model outputs could be new product types with associated cost curves in a variety of use categories. Then, just as the ICF Coal Model allows for 40 types of coal and new sources in each category, we could have an optimization model to minimize costs as its objective fuction, solving for prices, quantities, and other factors in each use category. Clearly, because processes can be used to produce different products, and because products can be produced by more than one process, the "engineering economics" necessary to get the cost curves, cross-elasticities and other relationships is complex. And there are serious problems in modeling demand, which itself is not independent of new product availability. But, as in the coal model, a wide variety of relationships can be programmed in as constraints, and such an approach is at least technically feasible. This approach has the advantage of extensive prior use in operations research models, so that many of the key software issues have already been addressed. It also is flexible and could allow for simultaneous demand/supply effects.

A Simulation Model. Here we would compile historical data on new products in use categores, and attempt to simulate the relationships between new product introduction and other economic and industry parameters (sales, prices, etc.). If we could construct a baseline model, which could be based upon historical relationships and changes over time in these relationships, we could then take the "outputs" of the innovation model (new products and associated cost in each use category) and simulate their sales and economic impacts over time. A particular problem is understanding to what degree new products are substituting for existing products in a use type, as opposed to enlarging markets overall. Although flexible, a drawback of this approach is its complete dependence upon historical relationships and its lack of theoretical underpinning.

Either of these model types would have to be contructed separately for each industry segment or product-type category. Either could be tied to an input-output model to test macroeconomic impacts (in either direction), but tying chemical industry segments to each other and to an input-output structure is a difficult and complex but technically possible task.

To construct an industry model of the chemical industry in either form described above, is a time-consuming and expensive task, especially as the number of product types, use types, or industry segments increase. Although difficult to estimate, either would take 12 to 18 months and cost around $500,000. Then, if the industry model were to be tied through an input-output model to a macroeconomic model, another 12 to 18 months and approximately $500,000 would be needed.

With these kinds of time and resource requirements, EPA must have reasonable expectations that chemical industry innovation can usefully be modeled at all before undertaking large industry modeling. Also, EPA should first be considering a small-scale demonstration effort of the various models to test their feasibility and then step-wise additions to the work with tests at each stage.

The following section further explores the chemical industry innovation process and how it might be modeled.

Modeling the Innovation Process

Before presenting our tentative ideas on how to attempt to model the innovation process in a framework which allows for determination of consideration of TSCA impacts, we should be clear on several points:

- No useful formal analytic tool can be constructed using publicly available data alone--or in time for the notice requirements economic impact analysis.

- It would be a bad idea to begin the "downstream" modeling of the industry and economy without some confidence that the innovation component can be modeled.

- The appropriate approach would be a small-scale (small-risk) attempt to develop an innovation model for one high R&D industry segment and to develop specificatons for its interface with an economic simulation model of that industry segment. This would require original data collection from industry (as detailed below); would take about nine months; and should cost on the order of $100,000. And it may wind up proving that because of lack of data and inability to translate qualitative judgments and TSCA effects into the model, a useful model cannot be constructed.

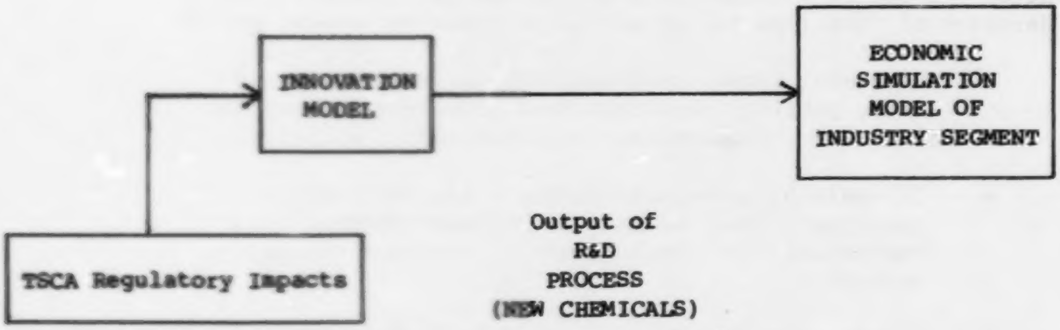
- Within the industry segment chosen, a great deal of specific work must occur in three categories:

  -- How the R&D/commercialization decisions (Blocks 1-4) have been made in the past and how they are being made today (necessary for the innovation model).

  -- How TSCA regulatons could or would affect these decisions (necessary for the innovation model).

  -- Case studies of prior new product introductions and their effects; creation of life-cycle profiles (necessary to construct the linkage between the innovation model and the industry model).

Framework for Modeling. We have argued that it is necessary to model the "innovation" model separately from any general model of an industry segment, and that to test TSCA impacts, the outputs of an innovation model must drive a more general economic impact model. In our view, this effectively precludes using a micro-econometric model structure, however large. Instead, we envision an economic simulation model which simulates industry performance based upon current relationships and trends in major economic variables and financial and economic production/use categories. We recognize the compexity of this task as applied to the chemical industry, where production processes, products, and uses form complex patterns.


INNOVATION MODEL
ECONOMIC SIMULATION MODEL OF INDUSTRY SEGMENT
TSCA Regulatory Impacts
Output of R&D PROCESS (NEW CHEMICALS)

The remainder of this section addresses how the innovation process could be modeled.

The Innovation Model

Blocks I and II: R&D Resource Allocation. The first major set of decisions we wish to model within a particular SIC code or other industry segment is the capital budgeting decision by which resources are allocated, first to R&D vs. other uses and then to product development R&D within all R&D resources. An attempt would be made to couple historical data on R&D expenses with new product payoffs and to solicit information from decision-makers and industry experts as to:

- How R&D funds are allocated;
- How probabilities of project success are assessed and what "hurdle rates" are employed;
- How decision makers mix projects with different risk/payoff profiles into an R&D "portfolio";
- How timing is factored into the decision;
- Whether products would be patented, labels registered, etc.; and
- What assumptions are made about competition if a successful product is brought to market.

This would have to be done largely through personal interviews. We have been unable to locate any previous work or set of data in these areas.

This initial allocation would focus upon three parameters which could be affected by TSCA:

(1) the ex ante view of costs, at each stage over the development process;

(2) the expected timing of events for new chemicals, and how delays affect returns on investment; and

(3) the expected profits from successful projects, the timing of these profits, and how profits might be affected by competitors' knowledge at the various steps of the development process.

This component of the model would produce an annual dollar allocation of resources to new product development in the industry segment as a function of the factors above. Historical data would be used to calibrate the model where possible.

Block III: Research. The assumption would be made that the research process itself was unaffected by TSCA; historical probabilities of technical success would be ascertained and used, either as fixed probabilities or dependent upon external (non-TSCA) factors (such as market growth, degree of product differentiation, etc.) A linear decline rate in probabilities, for example, could be used if it reflected historical realities.

Block IV: Commercialization. Then, the commercialization decision would be modeled, based again upon the expected costs, timing, and expected payoffs. It would be necessary here to examine patent protection, trade secrets, customer loyalty, time-to-market, and other competitive factors in a game-theoretic approach. This component of the model would attempt to replicate the actual decision making on commercialization in the industry segment--as a function of cost, delays, and payoffs.

Block V: Market Introduction. The final block would include how advertising, promotion, or other marketing expenses affect success in product introductions; the expected growth curves over time in the various use categories; and other post-commercialization effects.

The final result would be a simulation of the actual innovation process in that industry segment. Then, analyses of TSCA effects would be tested by inputting the estimated costs (at each time stage), delays (if any), and changes in competitive payoffs (but changing the probability distribution on payoffs). Ultimately, the objective would be to simulate the number of new products and their costs and payoffs over time without TSCA and to compare that to the number, costs, and payoffs with TSCA regulation. These results would then be linked to the industry-segment micro-econometric simulation model to test the economic impacts of greater or lesser numbers of new products with particular cost pay-off profiles.

Can such a model be usefully built? It is very possible that the data necessary to construct the model alone cannot be obtained from industry, and that the many approximations made in quantifying costs, risks, and payoffs would render the model useless as a tool. If so, in our view, the chemical new-product innovation process cannot be formally modeled.

We believe that EPA should either attempt to build such a model on a very small scale (one industry segment) or conclude that formal analytical approaches are not appropriate in this case. It does not make sense, in our view, to build a complex partial or general equilibrium model of the chemical industry, based upon econometric relationships if the initial factor of interest, product innovation--and the effects of TSCA on product innovation--cannot be incorporated into the model.

The possible limited use of a model of the latter type would be to test impact sensitivities to a range of gross assumptions about TSCA. For example, if R&D were contained in one set of equations, we might, say, assume that one-fourth, or one-half, or all R&D ceased as a result of TSCA and determine what impact this would have over time on the industry and economy. Because the impacts, at least in the shorter term, might be small, EPA might be able to establish that TSCA would be having no greater negative economic effects than those projected impacts.

BIBLIOGRAPHY

Summaries of books and articles have been taken from Cooper (19), Hill (40), and Kelly, et al. (50).

1. Adams, John G., "Research and Development of a New Drug," Food Drug Cosmetic Law Journal, Volume 26, January 1971.

FINDINGS/CONTENTS:

The golden age of drug discovery has reached a plateau and the present trend of a decline in new product introductions will continue. The former approach to drug research was to find a drug and then search for an illness that it could combat. This approach has now been reversed and this change from product-oriented to disease-oriented research will have a serious impact on drug research for both industry and government.

2. Allen, J.A., Studies in Innovation in the Steel and Chemical Industries. Manchester, England: Manchester University Press, 1967.

FINDINGS/CONTENTS:

Three studies of innovations are presented in the context of the prevailing state of the art in the areas in question, and the contemporary social and political environment.

Polyethylene and terylene, two new product innovations, and oxygen steelmaking, a new process innovation, were chosen to show the contrast between the two types of innovations and the subsequent difference in their development.

3. American Chemical Society, Chemistry in the Economy. Washington, D.C.: 1973.

4. Arthur D. Little Working Paper on formal approaches to measuring TSCA impact.

5. Ashford, N.A.; Heaton, G.R.; Priest, W.C.; and Lutz, H., The Implications of Health Safety and Environmental Regulations for Technological Change, Center for Policy Alternatives, Massachusetts Institute of Technology, January 15, 1979.

6. Backman, Jules. The Economics of the Chemical Industry. Washington, D.C.: Manufacturing Chemists Association, 1970.

7. Baily, Martin Neil, "Research and Development, Costs and Returns: The U.S. Pharmaceutical Industry," Journal of Political Economy, Vol. 80, No. 1, January-February 1972.

8. Bender, R.J., "Air Pollution Control: Its Dual Effect on the Chemical Industry," Power, Vol. 116, July 1972.

FINDINGS/CONTENTS:

Environmental legislation has prompted companies to innovate in their organizational structure; that is, to establish new departments devoted to controlling pollution and protecting the environment. Examples are given for DuPont, Water Resources Co., and Standard Oil.

9. Berenson, Conrad, The Chemical Industry: Viewpoints and Perspectives. New York: John Wiley & Sons, 1963.

Case studies of existing CPI firms.

10. Bloom, Barry M., "The Rate of Contemporary Drug Discovery," Lex et Scientia, Vol. 8, No. 1, January-March 1971.

Compares drug discovery rates for the U.S., U.K., Germany, France, Italy and Japan, and assesses the approval problems.

11. Burhenne, W.E. and Schoenbaum, T.J., "The European Community and the Management of the Environment," Natural Resource Journal, Vol. 13, 1973.

12. Burn, Duncan and Epstein, Barbara, Realities of Free Trade: Two Industry Studies. London: George Allen and Unwin Ltd., 1972.

Electrical engineering and the chemical industry.

13. Charpie, Robert, Technological Innovation: Its Environment and Management. Washington, D.C.: U.S. Department of Commerce, 1967.

14. "Big Drug Firms are More Innovative," Chemical and Engineering News, Vol. 51, October 29, 1973.

FINDINGS/CONTENTS:

Dr. David Schwartzman and Dr. Thomas R. Stauffer believe size will be the key if a company is to remain innovative in an industry that depends heavily upon innovation for survival. Also, research activity increases more than proportionately with firm size and large firms produce disproportionately more new drug innovations than smaller firms. Conclusions are based on a statistical analysis of a) the size of the research effort, b) the economies of scale in research, and c) the number of discoveries in the drug industry.

15. Choa, William Wing Fai, "The Relevance of Market Structure to Technological Progress: A Case Study of the Chemical Industry." Ph.D. Dissertation, Stanford University, 1977.

16. Clymer, Harold A., "The Changing Costs and Risks of Innovation in Drug Development," Research Management, Vol. 13, Sept. 1970.

FINDINGS:

The attrition rate of new drugs is increasing due to higher costs and longer development periods, the search for therapeutic breakthroughs (as a minor modification in an existing drug is subject to relatively the same cost and development periods) and the development of superior evaluation methodology.

17. Coleman, James S.; Katz, Elihu; and Menzel, Herbert, Medical Innovation: A Diffusion Study. Indianapolis: The Bobbs-Merrill Co., Inc., 1966.

18. Comanor, William S., "Research and Technical Change in the Pharmaceutical Industry," Review of Economics and Statistics, Vol. 47, May 1965.

A statistical examination of the pharmaceutical industry in an attempt to answer several questions concerning the relationship between firm size and propensity to conduct R&D, the relation between research and technical change, and the possible existence of economies of scale in R&D.

19. Cooper, Joseph D. (ed.), Regulations, Economics, and Pharmaceutical Innovation. Washington, D.C.: The American University, 1976.

20. Costello, Peter M., "The Tetracycline Conspiracy: Structure, Conduct, and Performance in the Drug Industry," Antitrust Law and Economic Review, Vol. 4, Summer 1968.

FINDINGS/CONTENTS:

The broad spectrum antibiotic tetracycline is taken from its inception to patent application through all its marketing phases as an example of how patent and licensing agreements can and do lead to a decline in competition and innovation.

21. DeHaen, P., New Product Survey, 1976: Newly Synthesized Drugs Introduced in the United States. New York: Paul deHaen, Inc., 1977.

22. Enos, John L., "Invention and Innovation in the Petroleum Refining Industry," in The Rate and Direction of Inventive Activity, ed. by the National Bureau of Economics Research, Princeton University Press, 1962.

    This paper examines the processes of invention and innovation as they have occurred in the petroleum refining industry, focusing on the relation between the two processes, the intervals between them, the returns to inventors and innovators, and the resulting changes in factor proportions in the industry.

23. Evaluation of the Possible Impact of Pesticide Legislation on Research and Development Activities of Pesticide Manufacturers, prepared by Arthur D. Little, Inc. for Office of Pesticide Programs, U.S. Environmental Protection Agency, EPA-540/9-75-018, February 1975.

24. Fisher, F.M. and Temin, P., "Returns to Scale in Research and Development: What Does the Schumpeterian Hypothesis Imply?," Journal of Political Economy, Vol. 81, No. 1, January-February 1973.

25. Freeman, Christopher, "Chemical Process Plant: Innovation and the World Market," National Institute Economic Review, No. 45, August 1968.

26. Freeman, Christopher, The Economics of Industrial Innovation. Middlesex, England: Penguin Books, 1974.

27. Freeman, Christopher, "The Plastics Industry: A Comparative Study of Research and Innovation," National Institute Economic Review, No. 26, November 1963.

28. Gibbons, M., "Factors Affecting Technical Innovation in British Industry," Industrial Marketing Management, Vol. 2, February 1973.

29. Grabowski, Henry G., *Drug Regulation and Innovation: Empirical Evidence and Policy Options*. Washington, D.C.: American Enterprise Institute, 1976.

30. Grabowski, Henry G., "The Determinants of Industrial R&D: A Study of the Chemical, Drug, and Petroleum Industries," *Journal of Political Economy*, Vol. 76, No. 2.

This paper reports the results of an empirical investigation into the determinations of R&D expenditures in three industries--drugs, chemicals, and petroleum refining. Determinants analyzed include past research productivity, output diversification, and availability of internal funding.

It is hypothesized that high past research productivity should have a positive effect on propensity to undertake research, that high degree of product diversification should also have a positive effect, and that R&D expenditures should be highly dependent upon changes in cash flows in the long run, but not in the short run. The hypothesis suggested is largely confirmed.

31. Grabowski, Henry G., and Baxter, N.D., "Rivalry in Industrial Research and Development," *Journal of Industrial Economics*, Vol. 21, No. 2, July 1973.

32. Grabowski, Henry G.; Vernon, John M.; and Thomas, Lacy Glenn, "The Effects of Regulatory Policy on the Incentive to Innovate: An International Comparative Analysis", in Mitchell, Samuel A. and Link, Emery A. (eds.), *The Impact of Public Policy on Drug Innovation and Pricing*. Washington, D.C.: The American University, 1976.

33. Grabowski, Henry G. and John M. Vernon, "Structural Effects of Regulation on Innovation in the Ethical Drug Industry," in Masson, R.T. and Qualls, P. (eds.), *Essays on Industrial Organization in Honor of Joe S. Bain*. Cambridge, Mass: Ballinger Publishing Co., 1976.

34. Greenberg, Edward, *et al.*, *Regulation, Market Prices, and Process Innovation: The Case of the Ammonia Industry*. Boulder: Westview Press, 1979.

35. Grether, David, "Market Structure and R&D," in Noll, Roger G., *et al.*, *Government Policies and Technological Innovation, Volume II-A, State-of-the-Art Surveys*, California Institute of Technology.

36. Gruber, William and Marquis, Donald (eds.), *Factors in the Transfer of Technology*. Cambridge: MIT Press, 1979.

37. Hamberg, D., "Size of Firm, Oligopoly, and Research: The Evidence," *Canadian Journal of Economics and Political Science*, Vol. 30, February 1964.

38. Hansen, R.W., "The Pharmaceutical Development Process: Estimates of Development Costs and Times and Effects of Proposed Regulatory Changes," in Chien, R.I. (ed.), *Issues in Pharmaceutical Economics*. Lexington, Mass: D.C. Heath, 1979.

39. Helms, Robert B. (ed.), *Drug Development and Marketing*, Washington, D.C.: American Enterprise Institute, 1978.

40. Hill, Christopher T., *et. al.*, *A State of the Art Review of the Effects of Regulation on Technical Innovation in the Chemical and Allied Products Industries* ("CAPI Project"), Vol. II, *The State-of-the-Art*, prepared by Washington University for the National Science Foundation under Grant No. RDA 74-200086) A01 (formerly DA-44092). St. Louis, Missouri: Washington University, Center for Development Technology, February 1975.

41. Hill, Christopher T. (ed.), *Federal Regulation and Chemical Innovation*. Washington, D.C.: American Chemical Society, 1979.

42. Hill, C.T. and J.M. Utterback (eds.), *Technical Innovation for a Dynamic Economy*, Elmsford, N.Y.: The Pergamon Press, 1979.

43. Jadlow, Joseph M., "Competition and 'Quality' in the Drug Industry: The 1962 Kefauver-Harris Drug Amendments as Barriers to Entry," *Antitrust Law & Economics Review*, Winter 1971-1972.

    Assesses the impact of 1962 Amendments to the Federal Food, Drug and Cosmetic Act. Finds considerable evidence that the Amendments have increased the cost of developing a marketable drug.

44. Jadlow, Joseph M., "Price Competition and the Efficacy of Prescription Drugs," *Nebraska Journal of Economics and Business*, Autumn 1972.

    Study of effects of 1962 Amendments to the Federal Food, Drug and Cosmetic Act on price competition. The author finds: "The legislation has been successful in reducing the flow of ineffective drug products to the market. It has, however, prompted an increase in drug research costs which has resulted in a decline in the private industrial development of important new drugs." He finds also that research costs of small drug firms have risen in greater proportions than those of large firms.

45. Jewkes, J.; Sawers, D.; and Stillerman, R., *The Sources of Invention*. New York: Norton, Second Edition, 1979.

46. Kamien, Morton I. and Schwartz, Nancy L., "Market Structure and Innovation: A Survey," a report prepared for the National Science Foundation, Evanston, Ill.; Managerial Economics and Decision Sciences, Graduate School of Management, Northwestern University, June 1974, p. 94. (Nine-page "Summary" and 108-page "Supplement Precis: Annotated Bibliography" are also available.)

A survey of economists' theories and empirical findings regarding market structure and innovation, concludes the relationship is still unresolved--better measures and data are needed. Finds that "many of the issues regarding the determinants of technical advances are intimately related to other facets of economic inquiry such as public goods, imperfect competition, uncertainty and search, decentralization and growth, which themselves are incompletely understood."

47. Kamien, Morton I. and Schwartz, Nancy L., "Risky R&D with Rivalry," *Annals of Economic and Social Measurement*, Vol. 3, No. 1, January 1974.

48. Kane, E.R., "Concerning the Economic Impact of Environmental Regulation on the Chemical Industry," Testimony before Joint Economic Committee, U.S. Congress, November 21, 1974.

49. Kelly, P. and Kranzberg, M. (eds.), *Technological Innovation: A Critical Review of Current Knowledge*. San Francisco Press, 1978.

50. Kelly, P. and Kranzberg, M., *et al.*, *Technological Innovation: A Critical Review of Current Knowledge, Vol. IV: Selected Literature Abstracts*. Georgia Institute of Technology, prepared for National Science Foundation, National Technical Information Service, February 1975.

51. Kennedy, Charles, "Induced Bias in Innovation and the Theory of Distribution," *The Economic Journal*, Vol. 74, September 1964.

52. Kuznets, Simon, "Inventive Activity: Problems of Definition and Measurement," *The Rate and Direction of Inventive Activity*, edited by the National Bureau of Economic Research. Princeton University Press, 1962.

53. Langrish, J.; Gibbons, M.; Evans, W.G.; and Jevons, F.R., Wealth from Knowledge: Studies of Innovation in Industry. London: McMillan Press, 1972.

Case histories of British industrial innovations.

54. Lasagna, Louis, "Research, Regulation, and Development of New Pharmaceuticals: Past, Present and Future," The American Journal of Medical Science, Vol. 263, January 1972.

55. Lasagna, L. and Wardell, W., "The Rate of New Drug Discovery," in Helms, Robert, B. (ed.), Drug Development and Marketing. Washington, D.C.: American Enterprise Institute, 1975.

56. Layton, Christopher with Harlow, C., and DeHoughton, C., Ten Innovations: An International Study on Technological Development and The Use of Qualified Scientists and Engineers in Ten Industries. London: George Allen and Unwin, 1972.

Compares British with U.S. and European innovation management.

57. Lebergott, S., Statement in U.S. Congress, Senate Subcommittee on Monopoly of the Select Committee on Small Business, Hearings on Competitive Problems in the Drug Industry, 93rd Congress. Washington, D.C.: U.S. Government Printing Office, February 1973.

58. Machlup, F. The Production and Distribution of Knowledge in the U.S. Princeton University Press, 1962.

59. Mansfield, Edwin, Industrial Research and Technological Innovation. New York: W.W. Norton for the Cowles Foundation for Research in Economics at Yale University, 1968.

60. Mansfield, Edwin; Rapoport, John; Schnee, Jerome; Wagner, Samuel; and Hamburger, Michael, Research and Innovation in the Modern Corporation. New York: W.W. Norton, 1971.

Study based on detailed firm data, one of a series of books by Mansfield on the "economics of technological change." Much of the data is drawn from the ethical drug industry.

61. Marquis, D.G., Innovation, Vol. 1, July 1969.

62. Marschak, Thomas A., "Strategy and Organization in a System Development Project," The Rate and Direction of Inventive Activity, ed. by the National Bureau of Economic Research. Princeton University Press, 1962.

63. Marshall, A. W., and Meckling, W.H., "Predictability of the Costs, Time and Success of Development," The Rate and Direction of Inventive Activity, ed. by the National Bureau of Economic Research. Princeton University Press, 1962.

64. Minasian, Jora R., "The Economics of Research and Development," The Rate and Direction of Inventive Activity, ed. by the National Bureau of Economic Research. Princeton University Press, 1962.

65. Montgomery, W. David and Quirk, James P., "The Market for Innovations," Noll, Roger G., et al., Government Policies and Technical Innovation, Volume II-A, State-of-the-Art Surveys, California Institute of Technology, prepared for the National Science Foundation under contract grant No. DA-39495-RDA-7307241, October 1974.

66. Morris, Simon Peter, "Models of Process-Diffusion and Entry in the U.S. Chemical Industry," Ph.D. Dissertation, University of Pennsylvania, 1975.

67. Mueller D.C., "Patents, Research and Development, and the Measurement of Inventive Activity," Journal of Industrial Economics, Vol. 15, 1966.

68. Mueller, Willard F., "The Origins of the Basic Inventions Underlying DuPont's Major Product and Process Innovations, 1920-1950," The Rate and Direction of Inventive Activity, ed. by the National Bureau of Economic Research. Princeton University Press, 1962.

An examination of the sources of the basic inventions underlying 25 of the most important of DuPont's product and process innovations, shows that DuPont has been more successful in originating improvement inventions than in discovering new products.

69. National Agricultural Chemicals Association, Industry Surveys, conducted by Ernst and Ernst. Washington, D.C.: 1971, 1973, 1975, 1977 and 1978.

70. Nobel, Patricia (ed.), The Kline Guide to the Chemical Industry, Fairfield, New Jersey: Second Edition, 1974.

71. Organization for Economic Cooperation and Development, The Chemical Industry 1971/1972, Paris: OECD, 1973.

72. Organization for Economic Cooperation and Development, The Measurement of Scientific and Technical Activities, OECD DAS/SPR 70.40, 1970.

73. Pavitt, K. and Wald, S., "The Conditions for Success in Technological Innovation," Paris: OECD, 1971.

74. Peltzman, Sam, Regulation of Pharmaceutical Innovation: The 1962 Amendments, Washington, D.C.: American Enterprise Institute for Public Policy Research, Second Printing, April, 1975.

75. Robertson, A.R.; Achilladelis, B.; and Jervis, P., Success and Failure in Industrial Innovation: Report on Project Sappho, London: Centre for the Study of Industrial Innovation, 1972.

76. Reuben, B. G., and Burstall, M.L., The Chemical Economy: A Guide to the Technology and Economics of the Chemical Industry, London: Longman Group Limited, 1973.

FINDINGS/CONTENTS:

A lengthy account of the chemical industry in the U.K. Coverage includes: the development of the chemical industry; the economics of the firms; the major sectors of the industry; problem with large scale chemistry; and the future of the chemical industry.

77. Sanders, Barkev S., "Some Difficulties in Measuring Inventive Activity," The Rate and Direction of Inventive Activity, ed. by the National Bureau of Economic Research. Princeton University Press, 1962.

Examines the problems associated with using each of three variables--inputs, rate of technological progress, and patent statistics--as measures of inventive activity.

78. Scherer, F.M., "Firm Size, Market Structure, Opportunity, and the Output of Patented Inventions," American Economic Review, Vol. 55, 1965.

Statistical study of the relationships between inventive activity and technological opportunity, firm size, product-time diversification, and monopoly power.

79. Schmookler, Jacob, Invention and Economic Growth, Cambridge, Mass: Harvard University Press, 1966.

80. Schumpeter, J.A., Capitalism, Socialism and Democracy, New York: Harper and Row, Third Edition, 1950.

81. Schwartzman, David, Innovation in the Pharmaceutical Industry, Baltimore: The Johns Hopkins University Press, 1976.

82. Schwartzman, David, The Expected Return from Pharmaceutical Research: Sources of New Drugs and the Profitability of R&D Investment, Washington, D.C.: American Enterprise Institute for Public Policy Research, 1975.

83. Foster D. Snell, Inc., Study of the Potential Economic Impacts of the Proposed Toxic Substances Control Act as Illustrated by Senate Bill S. 776, 26-31, February 20, 1975.

84. United Nations Educational, Scientific, and Cultural Organization, Measurement of Output of Research and Experimental Development, 1970.

85. Utterback, James M., "Innovation in Industry and The Diffusion of Technology," Science, Vol. 183, February 15, 1974.

State-of-the-art survey of factors which influence the process of innovation, including organizational environment, acceptance in the market, and diffusion of technology.

86. Vernon, John M. and Gusen, Peter, "Technical Change and Firm Size: The Pharmaceutical Industry," The Review of Economics and Statistics, Vol. 56, No. 3, August 1975.

87. Waddams, A. Lawrence, Chemicals From Petroleum: An Introductory Survey, New York: John Wiley and Sons, Inc., Third Edition, 1973.

An introduction to the petrochemical industry. Chemicals manufactured are classified according to source; an explanation of their applications, and the relationship between the petroleum chemical industry and related industries is given.

88. Wardell, William M., "British Usage and American Awareness of Some New Therapeutic Drugs," Clinical Pharmacology & Therapeutics, Vol. 14, No. 6, November-December 1973.

89. Wardell, William W., "Fluroxene and the Penicillin Lesson," Anesthesiology, Vol. 38, No. 4., April 1973.

90. Wardell, William M.; Hassar, M.; Anarekar, S.N.; and Lasagna, Louis, "The Rate of Development of New Drugs in the United States, 1963 through 1975," Clinical Pharamacology and Therapeutics, Vol. 24, No. 2, August 1978.

91. Wardell, William M. and Lasagna, Louis, Regulation and Drug Development, Washington, D.C.: American Enterprise Institute for Public Policy Research, 1975.

92. Williams, G.J., Letter to Sen. J.V. Tunney, p. 319-325 of Hearings on Toxic Substances Control Act of 1973 before Environment Subcommittee, U.S. Senate Commerce Committee, 1973.

APPENDIX C

DISCOUNTED CASH FLOW ANALYSIS

DISCOUNTED CASH FLOW ANALYSIS

The analysis presented here is based, in part, on Arthur D. Little's (ADL) preliminary economic analysis of the effects of premanufacturing notification (notice).[1] This appendix first reviews the purpose and scope of ADL's work and discusses the underlying methodologies as well as the results of their analysis. Then it provides a refined analysis using the same methodology.

PURPOSE AND SCOPE OF ARTHUR D. LITTLE WORK

The specific purpose of ADL's work was to estimate the cost to the chemical industry of completing the various sections of the notice form, and then to analyze the impact of the form. The analysis was hampered both by the lack of a finalized format for the notice forms and requirements, and the lack of appropriate economic and financial data on new chemical introductions. This affected both the statistical validity and the predictive accuracy of the analysis.

The ADL study was divided into four parts. The first was an industry overview providing general characteristics of chemical products and markets, types and sizes of firms, growth rates and the interaction and dependence of other industries on the chemical industry. It discussed company market share concentration in various segments, the value of raw materials and goods sold, and contained a description of the general flow of goods from primary raw materials to finished retail products.

The second part segmented the industry into those having similar economic, R&D and production characteristics. This was facilitated by using four-digit SIC codes which were arranged according to differences in the lines of business, relative size of the four-digit segment, and the degree of expected new chemical innovation. These segments were then characterized by market structure, financial condition, new chemical development (including patent activity), R&D expenditures, and new substance introduction, and by discussions with industry representatives and analysts at ADL. This section included the data on new chemical production and sales used in the impact analysis.

The third section described the regulatory requirements and estimated a range of costs for completing each area of the proposed notice form. This section used several major assumptions which affect completion costs, including the "likely response of a prudent firm," differences in the chemical use of the proposed product, and the ultimate distribution of the chemical.[2]

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[1] Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass.: December 1978).

The final section addressed the impacts of the notice requirements and included an economic analysis based on sales data previously presented and on notice completion costs. It discussed qualitatively the probable impacts on selected segments, and in a general sense, probable changes to the industry caused by notice requirements.

Results of the ADL Analysis

This section reviews the results of the ADL analysis and discusses the major assumptions and procedures for notice cost estimation and impact evaluation.

Exhibit C-1 summarizes the changes in the number of new chemicals introduced for various levels of notice costs calculated by ADL. The ADL report also stated that the impacts would be "relatively high" for small chemical manufacturing companies, and suggested several segments that would be impacted most severely because of a higher degree of innovation and smaller firm size.[3] These segments are listed in Exhibit C-2.

EXHIBIT C-1

IMPACT OF NOTICE COSTS ON NEW CHEMICAL INTRODUCTIONS

Type of Cost	Cost Range	Percentage Reduction in New Chemical Introductions
Minimum Mandatory Form Completion	$2,540 to $14,060	20 to 60
Maximum Mandatory Form Completion (total)	3,740 to 22,160	25 to 70
Optional Information Portion (total)	9,290 to 41,860	45 to 90

Source: Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass.: December 1978).

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[2] *Ibid.*, p. V-2.

[3] *Ibid.*, p. VI-5.

EXHIBIT C-2

INDUSTRY SEGMENTS MOST LIKELY TO FEEL NOTICE IMPACTS

Segment	SIC Code
Soaps and Detergents	2841
Surface Acting Agents	2843
Industrial Organic Chemicals, NEC	2869
Industrial Inorganic Chemicals, NEC	2819
Plastic Material and Resins	2821
Synthetic Rubber	2822
Toilet Preparations, Perfumes[a]	2844
Cyclic Crudes and Intermediates	2865

[a] ICF realizes this segment is not covered by TSCA.

Source: Arthur D. Little, Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass.: December 1978).

Notice Cost Estimation

Because of the uncertainties associated with the format of the notice form, ADL made several major assumptions when estimating the cost of completing the proposed notice form. These assumptions include:

- the likely response of a "prudent" firm: ADL assumed the firm will include as much information as necessary to make the form acceptable in terms of the amount and nature of the data supplied;

- the company size: ADL assumed a smaller firm will not be expected to provide the level of detail on the proposed notice form that a larger, more sophisticated firm could and would supply;

- the use of the chemicals: ADL assumed chemicals used as intermediates or with limited uses will not require as much detail on the notice form;

- the ultimate user of the chemical product: ADL assumed no regulating of ultimate users, which reduces the magnitude and complexity of the data gathering effort from secondary users of the chemical;

- the cost of preparing test data: ADL assumed that this was added to the cost of completing the form, even though the actual testing costs were not; and

- the hourly rate of employees engaged in completing the form: ADL estimated these at: managerial, $50/hour; professional/technical, $25/hour; clerical, $10/hour.

The actual cost estimation procedure grouped related activities together and estimated ranges for the amount of time necessary to complete the form for each pay category. Factors that affected the estimation of costs were grouped into four activity categories including data development, data collection, administration, and managerial review and supervision. These factors were then applied to each major segment of the proposed three-part form to provide a range of costs for Part I (General Information), Part II (Risk Assessment Data), and Part III (Risk Analysis and Optional Data). Alternative methods, such as grouping the efforts by type of information required, regardless of which part was affected, were not addressed.

ADL stated in their December 1978 report [4] that their estimation methods resulted in uncertainties of up to "50% or more" in the stated results. In their October 1979 report, the estimated cost range for the revised notice was $1,000 to $9,000 (over 50 percent less than the January form). These cost estimates, based on the January 10 estimates of the hours and pay rates and the October 16, 1979 form, provide a reasonable estimate of the probable completion costs for the reproposed form.

There may be additional non-direct costs associated with the completion of the form. These costs could include the loss of future revenues caused by a lack of confidentiality, additional testing, and other delays in the introduction of a new product. However, the variability and magnitude of these additional non-direct costs may be substantial and could radically affect new product innovation. It is beyond the scope of this portion of the discussion to address the probable magnitude of these costs.

Economic Analysis Assumptions and Methodology

The impact evaluation was preceded by economic estimates of the number of new chemicals developed annually, their rates of unit production growth, and their sales volume. ADL developed the estimates using a number of underlying assumptions which influenced the results and may have affected the impact evaluation.

ADL's estimate of the number of new chemicals introduced annually was based on several sources including the results of a Foster D. Snell survey, (Foster D. Snell, Inc., Study of the Potential Impact of the Proposed Toxic Substances Control Act as illustrated by Senate Bill S776, February 20, 1975), the number of new chemical patents issued, the EPA Inventory of Chemicals, the U.S. Department of Commerce-Current Industrial Reports, interviews with the publishers of "several leading commercial (chemical) directories" whose titles were not specified, and interviews with industry observers and representatives.[5] Four independent statistics were mentioned in the ADL report as a framework for the estimation of new chemical introductions, but the interrelationship of these data to each other and to the estimation methodology was not stated nor could it be inferred. In particular, these statistics, estimated from a sample of data from the Inventory of Chemicals and Current Industrial Reports, were:

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[4] Ibid., p. V-9.

[5] Ibid., p. III-7.

- fewer than an estimated 600 chemicals in EPA's Inventory of Chemicals (approximately 55,000 chemicals) had annual sales in excess of one million dollars per year;
- about an estimated one-half (or 30,000) of the chemicals in the Inventory of Chemicals had sales of less than 10,000 pounds per year;
- three percent of chemicals listed in "major chemical directories" (10,000 chemicals listed) are new each year, resulting in 300 new commercial chemicals whose annual sales exceed 1,000 dollars or 1,000 pounds;
- from the Current Industrial Reports, the four hundred sixtieth ranked organic chemical had sales of $100,000 and the fifty-ninth ranked inorganic chemical had sales of 1,000,000 dollars.

From these data and the aforementioned sources, ADL estimates of new chemical introductions are summarized in Exhibit C-3. ADL states that "very little information is available on this specific subject (of new chemical introductions), and that these estimates are presented solely for purposes of this preliminary analysis of TSCA premanufacturing notification impacts."[6]

EXHIBIT C-3

ADL ESTIMATES OF DISTRIBUTION OF NEW CHEMICALS INTRODUCED ANNUALLY[a]

Use	Under 1,000 pounds	Over 1,000 pounds	Total
R&D	2,000	--	2,000
Commercial	700	300	1,000
Total	2,700	300	3,000

[a] Estimates subject to ± 30% uncertainty.

Source: Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass.: December 1978), p. III-8.

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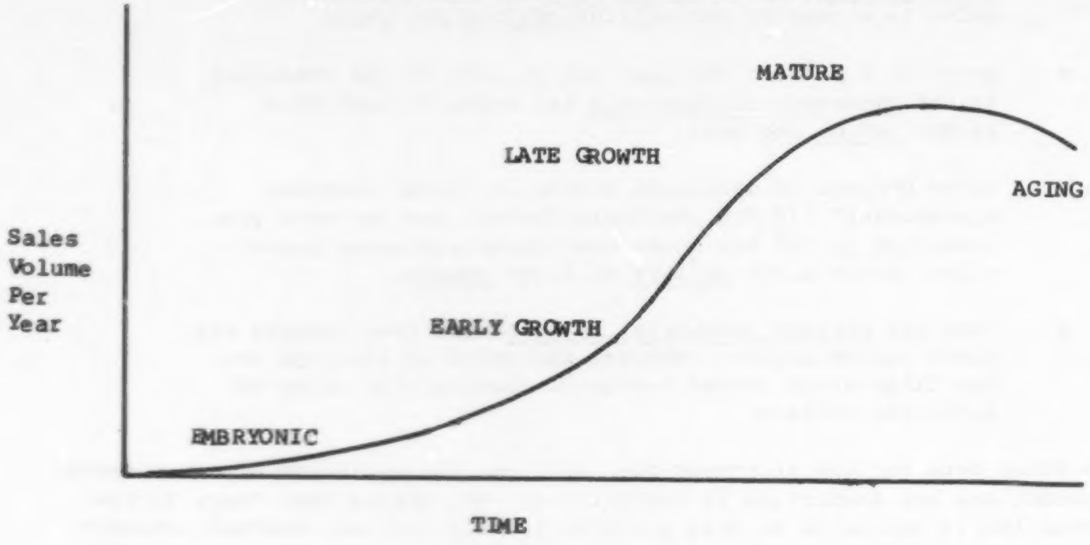
[6] Ibid., p. III-7.

The volume of a chemical's sales growth was assumed by ADL to follow a typical product life cycle path. Exhibit C-4 describes this path, indicating the sales per time period throughout the chemical's product life cycle.

EXHIBIT C-4

TYPICAL CHEMICAL SALES VOLUME LIFE CYCLE



The underlying theory and empirical evidence supporting the product life cycle concept is well documented elsewhere and will not be discussed here. It is important to note, however, that the shape and duration of the curve is strongly affected by the product under discussion. For example, the basic raw material chemicals such as oxygen, chlorine, and inorganic acids may never reach a declining growth phase, because there are no substitute products. At the other extreme, for new products in an industry sector where innovation is high and product substitution substantial, the growth curve may be nearly vertical for several years and suddenly fall to zero without a gradual decline. Thus, the use of this curve and associated growth functions as a model must be tempered by a reasonable understanding of the characteristics of the products and markets under analysis.

ADL selected 25 chemicals appearing in the Chemical Week Buyers' Guide which were added between 1973 and 1978. ADL acknowledged the bias of this sample: the Buyers' Guide is oriented toward the industrial segments, which implies higher sales for those chemicals sampled than the average of all 1,000 new commercial chemicals introduced each year. ADL did not adjust for this assumed bias. Exhibit C-5, taken directly from the ADL report, shows the data ADL used for analysis. ADL acquired the data on sales and first year of sale from telephone conversations with the manufacturers. The purpose of selecting a sample of chemicals was to arrive at a sales distribution which would indicate number of chemicals sold versus sales volumes in dollars.

EXHIBIT C-5

RESULTS OF TELEPHONE SURVEY OF "NEW" CHEMICAL PRODUCTION/SALES VOLUME[a]

Column	A	B	C		D	E
			1977 Sales Estimate		Estimated Value Per Pound (dollars)	First Year of Sale
	Chemical Number[b]	Manufacturer Number[b]	Pounds	Dollars (thousands)		
	1	1	1,000,000	650	.65	1965, 1978
	1	2	N/A	150	N/A	1969
	2	1	85,000	404	4.75	1950s
	3	1	46,000,000	11,040	.24	1950s
	4	1	N/A	N/A	N/A	1968
	5	1	N/A	N/A	N/A	1968
	6	1	225	24	107	1967
	7	1	150	116	775	1965
	8	1	N/A	N/A	N/A	1958
	9	1	N/A	10	N/A	N/A
	10	1	100,000	155	1.55	1968
	11	1	5,800	119	20.50	1972
	12	1	N/A	N/A	N/A	1968
	13	1	N/A	10	N/A	N/A
	14	1	65,000	520	8	1967
	15	1	400	24	60	1975
	16	1	1,000	45	45	N/A

17-25 No longer manufactured, or sold only for R&D purposes.

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[a] A new chemical for purposes of this survey was defined as one newly listed in the Chemical Week Buyers' Guide between 1973 and 1978. R&D sales of the chemicals were excluded.

[b] Numbers presented here are nominal. Different manufacturers, however, may each be denoted by "1".

Source: Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass.: December 1978), p. III-11.

To normalize the sales to a single year for analysis, ADL adjusted the sales amounts. They state:

> In order to place these chemicals on a consistent basis for purposes of the impact analysis, the sales values have been normalized to a 10th year sales figure. This has been done by assuming linear growth during this 10-year period. . . . The estimating procedure implies that the sales after five years would be half of those shown in [(Exhibit C-5, column 1)].[7]

It is apparent, however, that ADL did not use a linear normalization technique. A linear normalization technique achieves results different from ADL estimates.[8] A modified compound annual growth rate technique yields approximately the same normalized tenth year sales estimates ADL presented.[9] In the absence of yearly sales data, it is unclear which technique yields more accurate estimates. Often, the early stage of product sales growth is quite rapid, and an exponential growth function is more appropriate. In later years a linear function may be more appropriate due to slower growth. The use of an exponential (or compound annual) growth function implies that the sample chemicals are enjoying an upward sloping growth curve and that they are still in the early stages of their life cycle--a reasonable assumption.

Exhibit C-6 summarizes these findings, showing the ADL 1977 sales estimates (as shown previously in Exhibit C-5), the ADL "linear growth" normalized tenth year sales estimate as presented in their report, an ICF linear growth tenth year sales calculation, and an ICF compound annual growth tenth year sales calculation with appropriate annual compound growth rates.

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[7] *Ibid*., p. III-10.

[8] A linear extrapolation/interpolation technique assumes:

(1) 0 sales at introduction, year 0;
(2) 1977 sales estimates at the end of 1977, (Column C, Exhibit C-5);
(3) equal yearly growth increments calculated by dividing the 1977 sales estimates by total years of sales: (Column C, Exhibit C-5) divided by (1977 - Column E, Exhibit C-5).
(4) multiplying this yearly growth increment by 10 to calculate tenth year sales.

[9] A modified compound annual growth rate technique assumes:

(5) sales at the end of Year 1 are equal to one linear yearly growth increment as calculated above in (3);
(6) 1977 sales estimates are at the end of 1977;
(7) compound growth in sales occur at the appropriate constant compound rate between the end of Year 1 and 1977; and
(8) the tenth year sales estimate is the sum of the sales at the end of Year 1 as calculated in (5) and nine years of growth at the compound annual rate which yields the 1977 sales estimate found in Column C, Exhibit C-5 as calculated in (7).

EXHIBIT C-6

COMPARISON OF ADL AND ICF NORMALIZED GROWTH RATES

Column	A	B	C	D	E	
Chemical	1977 Sales Estimate ($ thousands)a/	Total Years Solda/	ADLa/ 10th Year Sales Estimate ($000)	ICF 10th Yearb/ Linear Growth Estimate ($000)	ICF 10th Yearb/ Compound Annual Growth Estimate	
					Sales ($000)	Growth Rate %
1	650	13	367	500	359	21.81
1	150	9	267	166	259	31.67
2	404	23	67	176	69	14.61
3	11,040	23	--	4,800	1,875	14.60
6	24	11	17	22	19	24.36
7	116	13	83	89	75	23.83
10	155	10	200	155	200	29.15
11	119	6	833	198	715	43.15
14	520	11	183	473	183	27.10
15	24	3	N/A	80	3,115	44.22
16	45	--	50	--	--	--

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a/Source: Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacture Notifications Requirements, (Cambridge, Mass.: December 1978).

b/Source: ICF estimates.

ADL constructed a cumulative distribution curve of annual dollar sales versus the cumulative percentage of chemicals sold. (ADL report Figure III-3, p. III-13). A major assumption made was that each of the 10 chemicals sampled fell into the respective decile of the probability distribution. ADL's resulting curve shows an S-shaped distribution.[10] Although the theories and statistical evidence for lognormal cumulative probability distributions and compound growth rates of products are fully accepted, we must recognize that these results are based on only 10 data points. Since ADL's figures are based on limited data, the uncertainty attached to their estimates is relatively large.

Impact Analysis Methodology

In order to analyze the impact of the notice, ADL employed a discounted cash flow analysis of the 10-year earnings streams of each of the sample chemicals. Major financial assumptions included a six percent return on sales, a 15 percent discount rate and a constant compound annual growth in sales of each chemical at the rate previously used in their normalization calculations, and depreciation charges whose net present value equaled the investment. Because they had no useful data about elasticity of demand, they assumed relatively elastic demand. Thus, the increased cost of the notice requirement did not result in a price increase; and a decrease in the quantity demanded did not occur.

Within the impact analysis are imbedded several major methodological assumptions:

1. The present value of the depreciation cash flow stream from capital investment in production facilities for the chemical, which is not captured in a discounted earnings stream, must have no impact on the decision to introduce a new chemical: Standard NPV analysis considers all after tax cash inflows and normally includes operating income, depreciation, depletion and amortization allowances, deferred taxes (if any), investment tax credits and the like. ADL did not include any cash inflows other than after tax operating income in their analysis, which may lead to underestimating actual returns and overstating notice impacts.

2. Notice costs must be on an after-tax basis to be reasonably compared to after-tax earnings streams: ADL used the before-tax notice costs, which will overstate the impacts by a substantial amount.

3. The sales of a particular chemical are not linked to the sales of other chemicals. Any two chemicals are independent in terms of sales growth, manufacturing, and prices; therefore, the removal or non-introduction of any product

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[10] This curve has the general form: $\log \frac{(p)}{1-p}$ where p is the cumulative probability of occurrence and varies between zero and one.

assumes no change in the overall distribution of products measured in terms of price/pound. It is possible that the imposition of small costs may not perturb the original distribution of chemicals by price/pound; but large costs, which could create large percentage changes in the number and type of new chemicals introduced in the market, may have unforeseen and unpredictable effects on the product/price distribution used in the analyses. It may cause a shift of the distribution to higher price/pound products or lower price/pound products. Given ADL's relatively severe impact, the methodology they employed, which assumed no shifts, may have been inappropriate.

4. New products face perfectly elastic demand. ADL assumed that regulatory costs would result in no change in the price of the new product and concomitantly no reduction in the quantity demanded. Evidence about new product pricing is contradictory. Comments by representatives of the specialty manufacturers about the uniqueness of, and immediate need by purchaser for, some new chemicals suggests that this assumption is wrong. Other public comment about the marginal technical improvement represented by some new chemicals and therefore the necessity to price them carefully, suggests this assumption is right. ICF believes that some new products face elastic demand and others do not.

   By assuming elastic demand for all new products, ADL neither understated nor overstated the impact of section 5. The reason for this is that in a competitive marketplace the increased price associated with the added costs will reduce the quantity demanded. Depending on the elasticity of demand it is possible that revenues could rise, fall, or stay the same at the new equilibrium.

The present values of the earnings stream of each chemical were arrayed in a cumulative distribution plot, which assumed each of the 10 chemicals represented 10 percent of new chemical introductions. This plot is shown as Figure VI-1, p. VI-11 of the report.

The methodology then compared the present values to the estimated notice completion costs. Where the notice costs exceeded the present value of the earnings stream, the chemical was assumed not to be introduced. From this comparison, and using the estimate of 1,000 new commercially introduced chemicals each year, ADL estimated the impact in terms of number of new chemicals that would be introduced. Their results are summarized in Exhibit C-7.

Impact Analysis Results

ADL's impact analysis was qualitative in nature. Except for the analysis on reduction in new chemicals introduced presented earlier in this section, there was no apparent analytical methodology associated with the results. In

EXHIBIT C-7

NEW CHEMICAL INTRODUCTION AS A FUNCTION OF NOTICE COMPLETION COSTS

TSCA (Notice) Costs	Number of Commercial Introductions[a]/
$ 0	1,000
5,000	700
10,000	500
20,000	300
40,000	100

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[a]/Annual rate of introduction in the absence of notice estimated to be 1,000 ± 30%.

Source: Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacture Notification Requirements (Cambridge, Mass.: December 1978), Table VI-3, p. VI-12.

summary, they suggested that the following impacts might occur as a result of notice cost imposition:

- As additional costs of new chemical introduction rise, the requirements for financial success will be larger, thus causing fewer new chemicals to be commercialized.
- The reduced number of new chemicals will, in turn, increase the required investment per new chemical because a smaller proportion of successful chemicals will support a larger proportion of unsuccessful chemicals.
- There may be changes in the R&D process.
- There will be increased spending for compliance (testing and administrative activities).
- There will be economic impacts in the chemical producing industries, the chemical consuming industries, and the national economy including the balance of payments. ADL did not specify the type, direction, magnitude, or nature of these impacts.

Summary

This section provided a summary of the ADL approach used in January 1979 and noted weaknesses in their methodology. The general directions of the impacts identified by ADL appear to be reasonable. Nevertheless, the apparent weaknesses in the analysis have led ICF to conclude that the magnitude of the impacts cannot be accurately quantified without first obtaining a comprehensive set of data about historical new chemical introduction. In the next section, we provide an alternative analysis of the available data having the benefit of more time and hindsight. Although we consider both analyses to be practically useless for identifying the impacts of notice requirements, the alternative analysis is presented in order to illustrate what can be done given that the necessary data are available.

ALTERNATIVE ANALYSIS

This section provides quantitative economic analysis similar to ADL's. The analysis can be replicated by those wishing to change the underlying assumptions, when and if additional data warrant such changes. Second, within the constraints of available data, this chapter presents a sensitivity analysis so the reader can appreciate the range of possible results.

A model which would accurately predict the impact on new product development would ideally have as its basis the capability to determine the impacts on product innovation. Such a model might consider the changes notice requirement options could produce in the cost and probability of success of commercialization of new chemicals and the consequent effects on R&D resource allocation. While changes in product innovation from notice requirement options could be conceptualized for heuristic purposes, the technical feasibility of this type of analytic approach presently is doubtful.

Today the majority of corporate investment decisions are made by formal or informal net present value (NPV) analysis.11/ This allows for maximizing returns on investments while considering the timing of investments and returns, the uncertainty of returns, and competing alternative investment proposals. In the case of new chemical product investment, the NPV methodology abstracts from a myriad of complex issues on resource allocation, innovation, and uncertainty, and yields a rational economic analysis based on readily available financial and market data. For these reasons, ICF has chosen a discounted cash flow (DCF) analysis which includes cash flow streams from both earnings and depreciation. Because the actual amounts of front-end investments in the sample chemicals used for this analysis are not known, the traditional NPV analysis will be modified. This model allows for varying the costs of notice completion, discount rates, sales growth functions, and returns on sales to test the sensitivity of new chemical introduction to changes in these factors.

Ideally, the scope of our analysis would include a statistically significant sample of chemical sales data which reflects the range of current and proposed product development and is believed to parallel the expected commercial success/failure ratio for new products in every segment of the industry. It would encompass a representative sample of sales data that allows for an accurate probability distribution of sales volumes for all sectors of the chemical industry. In reality, we realize the limitations of the ADL data and the few additional pieces of information available from industry responses. Yet, the methodology we are using easily allows for "updating" the analysis as additional appropriate data are made available.

11/A more complete discussion of NPV analysis may be found in the subsection: NPV Methodology.

SUMMARY OF RESULTS

Exhibit C-8 summarizes the results of the economic analysis. It shows both the "base case", considering the average impact that would be felt by the entire chemical and allied products (SIC 28) industry, and the results of sensitivity analyses on the major influential factors (discount rate, notice cost, and return on sales). Because of data limitations the range of these impacts could be larger. Moreover, as discussed earlier, it is unclear whether the sample data is biased towards high or low volume chemicals, and thus inaccurately reflects notice impacts.

The results in Exhibit C-8 are highly sensitive to changes in the assumptions used. For example, if a different data sample was used where the median chemical revenue stream was lower, the results could indicate a larger reduction in annual new chemical introductions. Although the varied parameters in the sensitivity analysis are independent of each other, industrial and market characterstics of particular sections of the chemical industry can be most accurately evaluated by changing several parameters at once. The effect of jointly varying several parameters is synergistic, and can change the expected reduction of new chemical introductions from two percent to 40 percent or more. The remainder of this section discusses the assumptions, methodology, and results of the economic analysis.

EXHIBIT C-8

SUMMARY OF IMPACTS OF NOTICE COSTS TO NEW CHEMICAL INTRODUCTIONS--BASE CASE AND VARYING MAJOR ASSUMPTIONS

After-tax Notice Cost	Discount Rate	Return on Sales	Percent Reduction In New Chemical Introductions
$2,500[a]	15%	6%	2
$500 - 4,500	15%	6%	0.5 - 5.0
$2,500	10 - 45%	6%	1.0 - 7.0
$2,500	15%	4 - 10%	0.5 - 5.0
$4,500	45%	4%	24
$20,000	15%	6%	30

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[a] Base Case, notice cost is expressed in after-tax cost (see subsequent pages).

ECONOMIC ANALYSIS ASSUMPTIONS AND METHODOLOGY

The utility of an economic analysis based on limited data hinges on how accurately the sample's distribution of data represents the actual distribution of the population under study. For example, assuming a population of 1,000 new chemicals (or larger) that have a typical lognormal distribution of sales growth, if we have a random sample of 30 or more chemicals, the distribution of the sampling statistics may approach the actual population distribution quite closely. Ultimately, the only way to test a particular sample's accuracy is by empirical tests--gather more random data and see if the statistics change drastically. We must assume from the outset that the chemical samples we are using for this analysis are randomly chosen and accurately represent the population of new chemical introductions. Without this basic underlying assumption, no further analysis can be performed. For this reason, we feel that the sample we are using is limited and thus may not accurately predict economic behavior. Nevertheless, the understandable reluctance of the industry to provide additional data has necessitated that we use the data at hand. The use of sensitivity analysis may compensate for any bias in the sample data by creating a range of possible outcomes which lie at the far ends of possible outcomes. Understandably, a subjective element is introduced when deciding what is a reasonable and relevant range for the variables in the analysis. The following subsections discuss the assumptions and coefficients of the important variables used in the analysis.

NPV Methodology

The net present value (NPV) method of investment analysis discounts all cash inflows (the returns) at the marginal cost of capital, and subtracts the initial or discounted outlay as shown in Equation (1).[12] For this analysis, the value of the investment (I) is not known, and as a result the actual NPV or changes in NPV as a result of additional investment costs from notice completion cannot be calculated. Assuming that I is zero, then the present value of cash inflows calculated would be the net present value. Whenever this NPV is exceeded by a notice cost, the chemical would not be introduced. Investments are greater than zero, however, so for any given discount rate the NPV must be less than the PV of cash inflows, although this value cannot be calculated with the available data. Using the assumption that I=0 will, of course, understate the impacts of notice costs somewhat for any given discount rate.

$$\frac{R_1}{(1+r)^1} + \frac{R_2}{(1+r)^2} + \ldots + \frac{R_n}{(1+r)^n} - I = NPV \qquad (1)$$

Where R = Return (revenues-expenses)
I = Investment
r = marginal cost of capital (or desired return rate set by company)
n = year of final return.

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[12] The marginal cost of capital is used by firms who follow a value-maximizing strategy. A higher discount rate, often called a "hurdle" rate, leads to a less-than-maximum investment strategy, and is often used where the company faces capital rationing.

For example, suppose the PV of cash inflows from chemical A were $10,000. If an investment of zero is assumed, a notice cost of $10,000 could be imposed before the chemical would not be introduced. Of course, investment is greater than zero so the NPV of chemical A is less than $10,000. If the accounting method of depreciation of assets were known, the investment from depreciation cash flows could be calculated. Several methods of accelerated and straight line depreciation are currently in use, however, and without knowing which method is used the original investment cannot be accurately calculated. Because the depreciation cash flow here is estimated as a percent of sales, a further estimation of the original investment cannot be made with a high degree of assurance.

There is a modified methodology which will provide another way to look at the impact of notice costs, however. This is the internal rate of return (IRR) method, which applies a discount rate that equates the present value of cash outflows (the investment) with net cash inflows (the returns), as shown in Equation 2.[13]

$$\frac{R_1}{(1+r)^1} + \frac{R_2}{(1+r)^2} + \ldots + \frac{R_n}{(1+r)^n} - I = 0 \qquad (2)$$

where R = Return (revenues-expenses)
I = Investment
r = internal rate of return (IRR)
n = final year of returns

---

[13] Both the IRR and NPV methods are based on the principle of discounting, which assumes the opportunity, but not the necessity to reinvest all return cash flows at the discount rate. The NPV method implies the opportunity (but not the necessity) exists to reinvest at the company's chosen discount or hurdle rate. The IRR method implies the opportunity (but not the necessity) exists to reinvest at the calculated rate of return for the proposed investment. Both criteria give the same accept-reject decision for specific projects, but under certain conditions of different amounts and timing of return cash flows may rank projects differently. Weston and Brigham (F. Weston and E. Brigham, Managerial Finance, 5th ed., p. 274, Dryden Press, Hinsdale, Illinois, 1976) argue that if management is seeking to maximize the value of the firm, the project with the higher NPV will contribute more to the firm. Because there are also questions whether reinvestment opportunities will actually be available at the calculated IRR, the NPV method is used more often by industry.

We can use the IRR method to show changes in the assumed internal rate of return in the following fashion:

- Assume the IRR equals some value;
- Calculate the PV of net cash inflows from net income and depreciation. The resulting number, by definition, is equal to the original investment;
- Add notice costs to the original investment amount;
- Calculate the new IRR that will make the PV of net cash inflows equal the new investment amount; and
- The difference in IRRs is the change in return that would occur if notice costs were imposed.

This allows us to see the relative impact of notice costs on proposed new chemical introductions as a change in IRR.

For example, assume an initial IRR of 15 percent and a PV of cash inflows of $10,000.

From equation 2, we know:

$$\$10{,}000 - I = 0 \quad \text{or} \quad I = \$10{,}000 \tag{3}$$

If we impose a notice Cost of $1,000, then:

$$I' = \$11{,}000 \tag{4}$$

From this, we can find the new IRR (IRR') that gives a PV of cash inflows of $11,000. In this example, IRR' might equal 13.5 percent. The change (IRR - IRR'), or -1.5 percent, is the relative economic impact of the notice cost. For smaller PVs, the relative impact would be larger, for larger PVs, the impact would be smaller. Additionally, the relative impact will depend on which initial IRR is chosen.

Discount Rate

The discount rate for ongoing projects is a function of the firm's average cost of capital. If we assume that the technical and commercial risks of new projects do not differ from those of ongoing projects, we could use this cost of capital for new projects when discounting. However, it is readily apparent that new product introductions vary widely in terms of commercial and technical risk, from relatively minor chemical modifications of an established product to radically new compounds with no sales guarantees. Firms typically establish a higher discount rate for higher perceived risk introductions. This explicitly takes into account the higher probability of commercial failures. Only prospects with expected high rates of return will be commercially introduced where the probability of poor sales is large, in order to cover the cost of a larger number of failures. For a firm, this requires factoring into an individual commercialization analysis some failure rate or probability distribution of expected failure, which results in the adjustment to the required rate of return. Discussions with industry representatives and comments received in response to Reproposal of Premanufacture Notice Form and Provisions of Rules (44 Federal Register 59764, October 16 1979) indicate a range of 10 to 45 percent discount rates are used by firms for new chemical introduction analysis. We assume these to be reasonable and have chosen 10 percent, 15 percent, 30 percent and 45 percent as representative discount rates for analysis purposes. ADL used 15 percent across all segments.

Sales

As discussed earlier, the use of a particular growth function for sales must be tempered by a reasonable understanding of the markets and products under analysis. If the sample is assumed to be random the sales behavior of the chemicals will mirror the industry aggregate behavior. In lieu of actual data on yearly sales for sample chemicals, the use of a general product life cycle growth model is then reasonable, if it can be ascertained where in the life cycle the chemical fits. For the sample data this is not possible. On the other hand, linear or exponential growth models may be more appropriate for portions of the product's life, especially in the early phases of growth. Caution must be exercised when using exponential or linear estimators, because these models have no practical limit to growth, which can radically affect the present value analysis where the growth rate differs widely from the discount rate, or the data are extrapolated to several times the known period of sales.

Industry experts such as Henry Grabowski, John Vernon and Christopher Hill (see Appendix B Bibliography, especially 30, 32, 40) differ on what the average life cycle of a new chemical looks like; therefore, both linear and exponential growth models, normalized to 10 (linear) or 11 (exponential) years, have been chosen for use here, to provide some sensitivity to changes in growth rates. In order to calculate a 10- or 11-year stream of returns, estimates of sales for each of the first 10 or 11 years of sales were made as follows:

- Linear interpolation/extrapolation: The 1977 sales figures are divided by the number of years the chemical has been sold. The resultant number is considered to be the sales at the end of Year 1, and is increased by that same amount each succeeding year. For example, if a chemical had been sold for 13 years, sales in Year 1 are equal to one-thirteenth (1/13) of 1977 sales, sales in Year 2 equal two-thirteenths (2/13) of 1977 sales, and so forth. Exhibit C-9 illustrates this example.
- Exponential interpolation/extrapolation: A modified compound growth function is created by using a one year linear growth rate for one year. Knowing the sales at the end of Year 1 and 1977, we solve for the particular compound rate which gives both end points. For example, if a chemical had sales of 100 in 1977 and had been sold for 13 years, sales at the end of Year 1 would be 7.69, and the compound annual rate of growth would be 23.83 percent for the 12 years between the end of Year 1 and Year 13. By

EXHIBIT C-9

LINEAR GROWTH MODEL

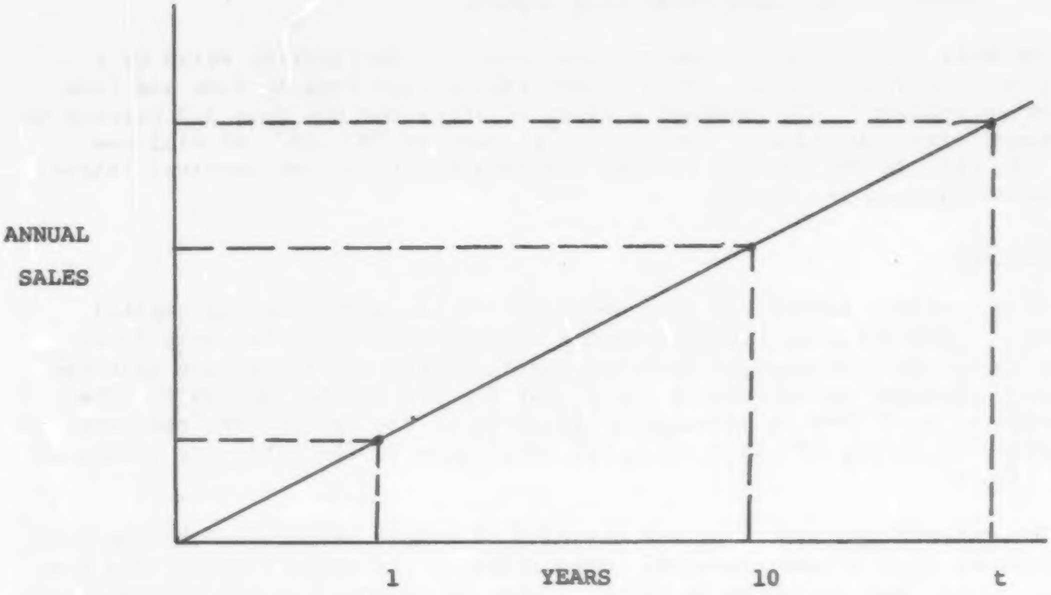
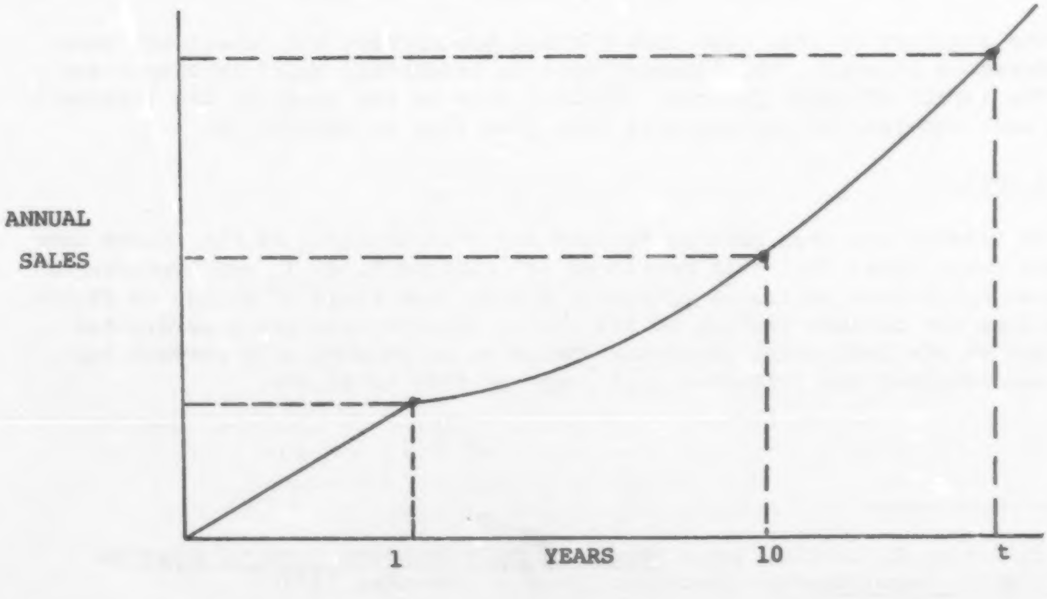


EXHIBIT C-10

EXPONENTIAL GROWTH MODEL



interpolation, sales in Year 10 (nine after the end of Year 1) are 52.66, using 7.69 as starting sales, at the end of year 1 compounded at 23.83 percent per year. Exhibit C-10 illustrates this example.

From the sale figures, net income is calculated by multiplying sales by a return on sale (ROS) factor. This factor varies from firm to firm and from product to product. ADL reported a range of after-tax ROS from 2.3 percent to 12 percent with the industry average 7.1 percent in 1977.[14] We will use .04, .06, and .10 ROS factors to test the sensitivity of new chemical introduction to changes in returns.

Depreciation

Cash in-flows also occur from depreciation tax deductions on capital equipment. Exhibit C-11 illustrates the depreciation after-tax cash flows from selected basic/commodity chemical manufacturers (23 firms) and selected specialty chemical manufacturers (20 firms) for the period 1974-1978. The depreciation cash flow is calculated (adjusted by the appropriate tax rate) as a function of sales, making it directly comparable to the after-tax return on sales figures.

The current year sales of the majority of sample chemicals indicate they are probably high volume, low-cost commodities in the current year. The normalized tenth year estimates by either linear or compound growth method result in nine out of 12 chemicals with sales in excess of $100,000. Therefore, we suspect that these are capital intensive chemicals and the more capital intensive depreciation after-tax cash flow factor of 2.62 percent of sales has been used in this analysis. The depreciation cash flow is added to the ROS flow, and the sum is discounted at the discount rate.

We could have ignored the depreciation stream by assuming it equaled the investment. However, this would not be analytically sound.

The addition of this cash flow without subtracting the investment tends to understate impacts. The underestimate is relatively small in comparison with the impact of other factors. Without data on the level of the ivestment it is more accurate to include this cash flow than to exclude it.

Notice Costs

No attempt has been made to perform any cost analysis of the notice completion costs other than that mentioned in Chapters 5, 6, 7, and Appendix A. The most up-to-date estimates provide a notice cost range of $1,000 to $9,000, which does not include testing of any type. Because this was a before-tax cost and we are performing after-tax analysis, we assumed a 50 percent tax rate and obtained the after-tax cost range of $500 to $4,500.

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[14] Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass.: December 1978).

EXHIBIT C-11

REPRESENTATIVE DEPRECIATION CASH FLOWS OF CHEMICAL MANUFACTURERS AS A PERCENTAGE OF NET SALES: 1974-1978

23 Basic Chemical Companies

Range of Depreciation	5.54 to 6.60% of sales
Average	6.30%
Range of Tax Rates	41.3 to 41.8%
Average Tax Rate	41.6%

After-Tax Depreciation Cash Flow = .416 x 6.3% = 2.62% of sales

20 Specialty Chemical Companies

Range of Depreciation	2.56 to 2.73% of sales
Average Depreciation	2.59%
Range of Tax Rates	44.3 to 46.1%
Average Tax Rate	44.9%

After-Tax Depreciation Cash Flow = .449 x 2.59% = 1.16% of sales

Source: Value Line Investment Survey, A. Bernhard & Co., New York, N.Y., 1980.

RESULTS OF THE ECONOMIC ANALYSIS

Overview/Base Case Results

The base case results provide the most probable results of notice cost imposition. These results can be used as a standard to assess the relative changes in the results due to sensitivity analysis. As shown in Exhibit C-14, if the after-tax cost of completing the notice is $10,000, fifteen percent of all new chemicals that would have been introduced will not be. Because the expected after-tax cost of the manufacturer's notice is $2,500, the expected reduction in new chemicals is two percent. In the subsequent paragraphs the derivation of the curve shown in Exhibit C-14 is provided.

The base case variables are assumed to be:

- 15 percent discount rate;
- 15 percent IRR;
- six percent ROS;

- $2,500 (average) notice completion after-tax cost;
- 2.62 percent of sales depreciation cash flow; and
- exponential sales growth model compounded for 11 years.

Exhibit C-12 summarizes the data taken from the ADL report and the Reilly Tar and Chemical Company, giving sales or sales estimates in the first and tenth years, and 1977.[15] It shows the ADL compound growth estimate normalized to the tenth year, the ICF compound growth estimate for the tenth year and the number of years the chemical has been sold, the number of years it was compounded to achieve the ICF estimate, and the resulting compound interest rate expressed in percent growth per annum. Exhibit C-13 presents the PV analysis for this data. It summarizes the first and tenth year sales estimates, present value of cumulative sales for 11 years, the resulting ROS for each chemical, and the adjusted return after a $2500 cost imposition.

Exhibit C-14 shows graphically a cumulative distribution of the present values for the sample chemicals (from Exhibit C-12, Column D) with the assumption that each sample chemical represents approximately eight percent of total chemicals sold, with each sample falling into its respective eight percent bracket from lowest to highest sales.

Exhibit C-15 shows how the imposition of a $2,500 additional cost would change an assumed 15 percent IRR for the range of PVs found in the base case (from Exhibit C-12, Column D). For example, if the present value of returns was $10,000 before imposition of notice costs, the imposition of those costs would reduce the IRR by approximately five percent. Thus the new IRR would be 10 percent. As expected, the impact of the $2,500 cost is most significant for chemicals with smaller sales volume histories and lower present values.[16]

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[15] Data are from the Reilly Tar and Chemical Company response to the reproposal notice (44 Federal Register 59746, October 16, 1979).

[16] The basic sales growth data from which all subsequent calculations were made are contained in the Supplement to this appendix which follows. It is not necessary to refer to these data for the discussion of the results of the analysis, however.

EXHIBIT C-12

SUMMARY OF DATA USED IN BASE CASE ANALYSIS

Column	A	B	C	D	E	F	G
Chemical	1st Year Estimated Sales	1977 Sales	Years Sold	ADL 10th Year Estimated Sales	ICF 10th Year Estimated Sales	Years Compounded	Annual Growth Rate
1	$2,180	$24,000	11	$17,000	$19,300	11	24.36%
2	8,920	116,000	13	83,000	75,600	12	23.83%
3	17,560	404,000	23	67,000	69,000	23	14.60%
4	16,630	183,000	11	183,000	183,000	10	27.10%
5	15,500	155,000	10	200,000	200,000	9	29.15%
6	8,000	24,000	3	N/A	311,000	3	44.22%
7	16,660	150,000	9	267,000	260,000	8	31.67%
8[a]	72,900	--	10	N/A	30,400	--	--
9	50,000	650,000	13	367,000	359,000	13	21.81%
10	19,800	119,000	6	833,000	715,000	5	43.15%
11[a]	155,040	--	10	N/A	189,000	--	--
12	480,000	11,040,000	23	N/A	1,875,000	23	14.61%

N/A = Not available.

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[a] Data from Reilly Tar and Chemical Company, no model used. All other chemicals from ADL report identified below.

Source: Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacture Notification Requirements (Cambridge, Mass.: December 1978); and ICF estimates.

EXHIBIT C-13

SUMMARY OF BASE CASE ECONOMIC ANALYSIS RESULTS

Column	A	B	C	D	E
Chemical	First Year Sales	10th Year Sales	Present Value of Sales	Net Cash Inflows[a]	Return After Added $2,500 Cost
1	2,180	19,300	36,560	3,151	646
2	8,920	75,600	145,950	12,581	10,081
3	17,560	69,000	189,830	16,363	13,863
4	16,630	183,000	316,990	27,325	24,825
5	15,500	200,000	325,500	28,058	25,558
6	8,000	311,000	348,450	30,036	27,536
7	16,660	260,000	394,540	34,009	31,509
8[c]	72,900	30,400	549,488[b]	47,366	44,866
9	50,000	359,000	745,510	64,263	61,763
10	19,800	715,000	818,430	70,549	68,049
11[c]	155,040	189,000	1,325,838[b]	114,287	111,787
12	480,000	1,875,000	5,191,370	447,496	444,796

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[a] Include six percent ROS + Depreciation Cash Flows (2.62 percent of Sales).

[b] Compounded for 10 years.

[c] Reilly Tar and Chemical Company data.

EXHIBIT C-14

BASE CASE RESULTS

CUMULATIVE PERCENTAGE OF CHEMICALS NOT INTRODUCED AS PMN COST RISES ASSUMING 15% RETURN REQUIRED

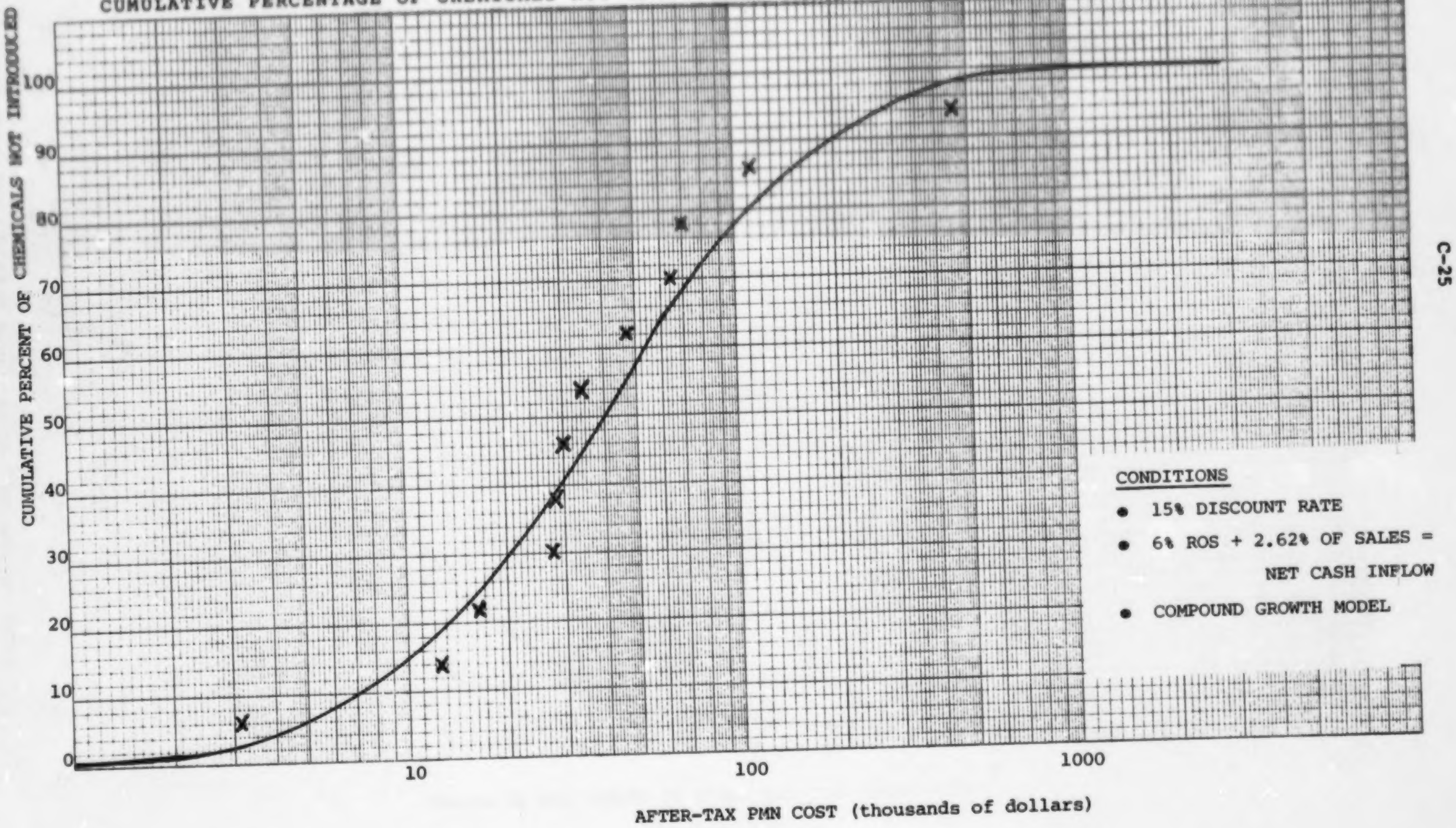
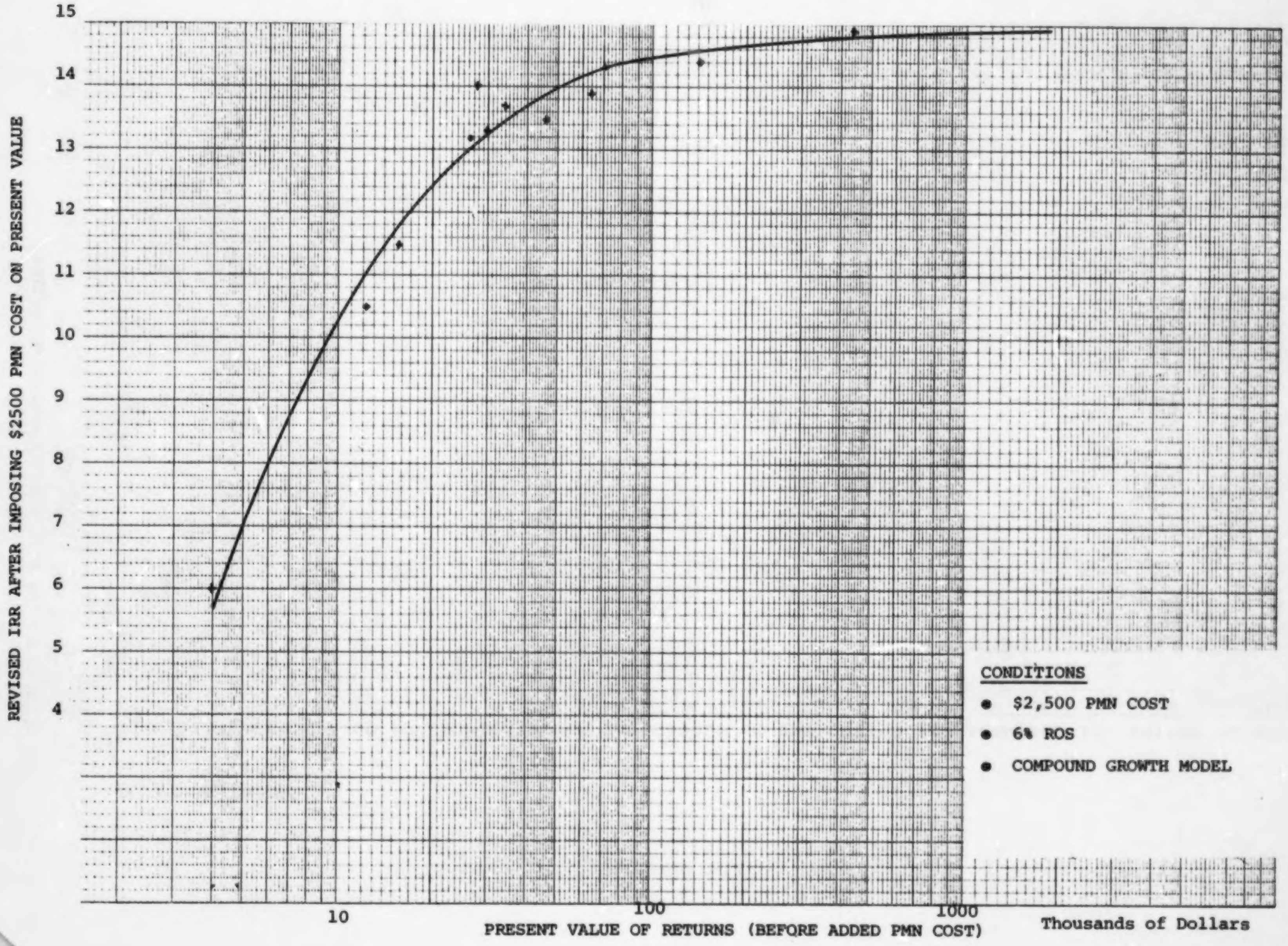


EXHIBIT C-15

CHANGE IN IRR CAUSED BY $2500 PMN COST IMPOSITION



Sensitivity to Changes in Discount Rate

In this portion of the analysis, we use discount rates of 10 percent, 15 percent, 30 percent, and 45 percent. This range is extremely wide, and it is unlikely that any firm's required rate of return will exceed these limits. Exhibit C-16 presents the present values for each chemical at the four different discount rates, before the $2,500 notice cost addition. Exhibit C-17 illustrates the change in shape and value of the cumulative sales curve for the four rates. This graphically illustrates the percentage of new chemicals that might not be introduced as a result of additional cost increases as the required rate of return increases. For example, varying the discount rate from 15 percent to 45 percent changes the reduction in new chemical introductions from two percent to seven percent if the notice cost is $4,500 after tax. Exhibit C-18 supports this illustration by showing the variation in the sensitivity of changes in IRR from a $5000 notice cost for different starting IRRs. This is above the maximum expected notice cost, but was chosen to clearly illustrate the adverse impact.

EXHIBIT C-16

SENSITIVITY OF CASH INFLOW PV TO DIFFERENT DISCOUNT RATES[a]

			PRESENT VALUE (Discount Rate)			
Chemical	First Year Sales ($K)	Tenth Year Sales ($K)	10%	15%	30%	45%
1	2.18	19.3	4,112	3,151	1,672	1,076
2	8.92	75.6	15,709	12,581	6,430	4,157
3	17.56	69.0	20,602	16,363	9,585	6,678
4	16.63	183.0	35,974	27,325	14,122	8,887
5	15.50	200.0	37,180	28,058	14,226	8,802
6	8.00	311.0	41,405	30,036	13,444	7,385
7	16.66	260.0	45,398	34,009	16,852	10,213
8	72.90	34.4[b]	57,312	47,366	29,444	20,401
9	50.00	359.0	78,801	64,262	34,968	22,987
10	19.80	715.0	97,018	70,549	31,822	17,628
11	155.04	189.0[b]	141,296	114,287	67,874	45,700
12	480.00	1,875.0	563,561	447,496	262,105	182,572

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[a] Cash inflow includes depreciation cash return at 2.62 percent of sales.

[b] Actual Sales data provided by Reilly Tar and Chemical Corporation.

EXHIBIT C-17

SENSITIVITY OF RESULTS TO CHANGES IN REQUIRED RATES OF RETURN (DISCOUNT RATE)

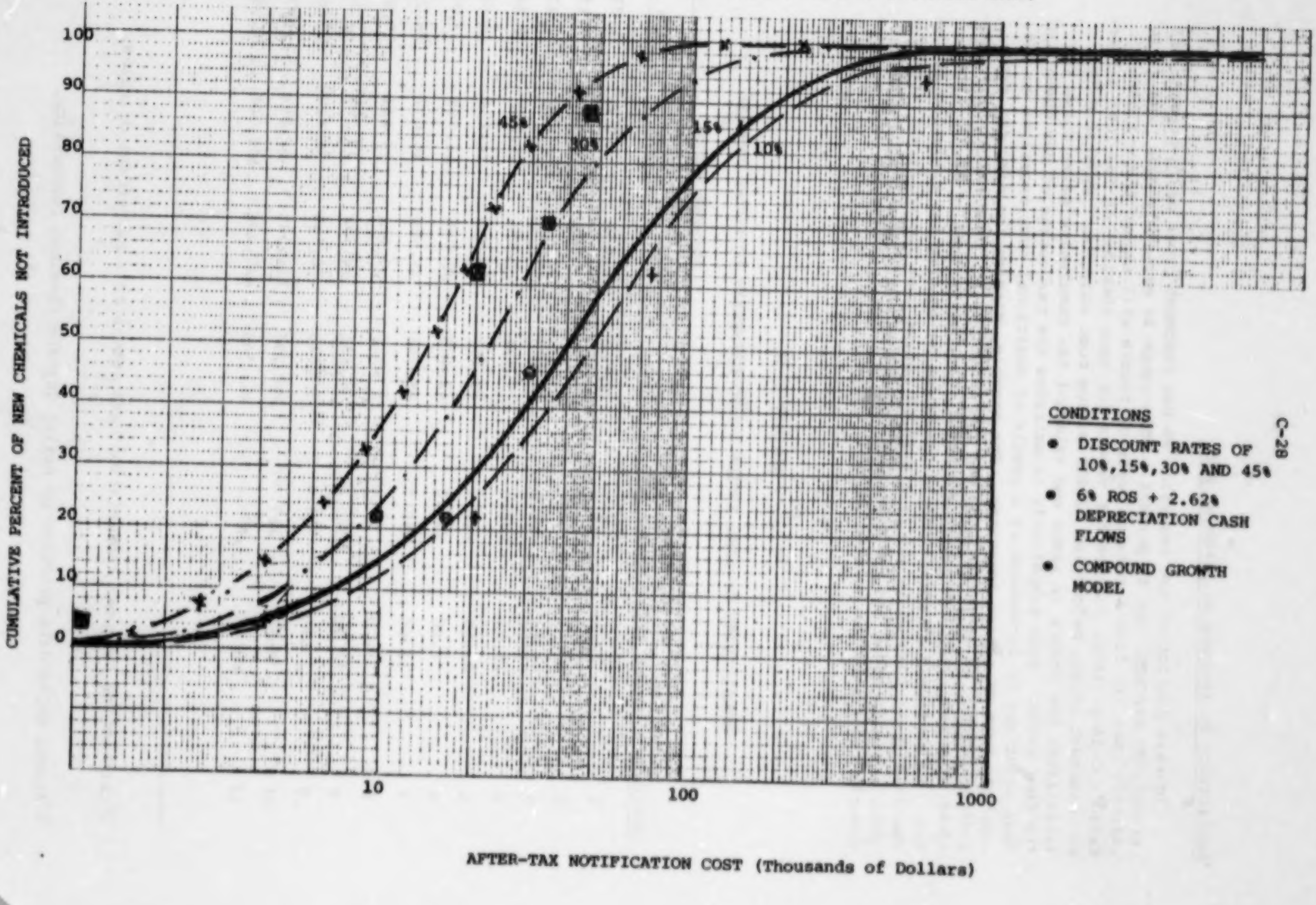

EXHIBIT C-18

SENSITIVITY OF CHANGES IN IRR FROM $5,000 PMN COST IMPOSITION

	10%			15%			30%			45%		
Chemical	IRR	ΔIRR	PV	IRR	ΔIRR	PV	IRR	ΔIRR	PV	IRR	ΔIRR	PV
1	a/	--	--	a/	--	--	a/	--	--	a/	--	--
2	4.5	-6.5	$15,700	6.50	-8.50	$12,100	15.75	-14.25	$6,400	a/	--	--
3	6.6	-3.4	20,600	9.50	-5.50	16,400	18.50	-11.50	9,600	24.5	-20.5	$6,700
4	6.8	-3.2	36,000	11.25	-3.75	27,300	23.75	-6.25	14,100	30.2	-14.8	8,900
5	7.0	-3.0	37,200	12.25	-2.75	28,000	22.80	-7.20	14,200	30.8	-14.2	8,800
6	8.5	-1.5	41,400	12.75	2.25	30,000	25.50	-4.50	13,400	31.5	-13.5	7,400
7	7.6	-2.4	45,400	12.50	-2.50	34,000	23.80	-6.20	16,900	32.5	-12.5	10,200
8	7.3	-2.7	57,300	12.00	-3.00	47,400	25.50	-4.50	29,400	34.8	-10.2	20,400
9	8.5	-1.5	78,800	13.20	-1.80	64,300	26.25	-3.75	35,000	37.2	- 7.8	23,000
10	9.2	-.8	97,000	12.75	-2.25	70,500	27.50	-2.50	31,800	38.6	- 6.4	17,600
11	9.4	-.6	141,300	14.10	-.90	141,300	27.75	-2.25	67,900	39.4	- 5.6	45,700
12	9.8	-.2	563,600	14.70	-.30	447,500	29.50	-.50	262,100	43.8	- 1.2	182,600

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a/ IRR is negative.

Sensitivity to ROS

Because return on sales (ROS) can vary widely between firms and among individual products, we have chosen to examine the sensitivity of the present value of cash inflows to a relatively wide range of returns. Returns for individual firms were reported by ADL and ranged from two to over 12 percent of sales. It is reasonable to expect for all chemical firms the range will be greater for all products in a single year, as some products will lose money and some will be extremely profitable. Over a longer period of time, however, the average profits from a wide portfolio of chemicals must approach the industry average if the chemicals are a representative sample of chemicals sold. Profit margins have not changed drastically over the past two decades, as Exhibit C-19 indicates. Because profit margins have not changed greatly, the values of four percent, six percent, and 10 percent have been selected as a reasonable and representative range for ROS.

EXHIBIT C-19

PROFITABILITY OF THE U.S. CHEMICAL INDUSTRY: 1964-1977

Year	Net Sales ($ million)	Income Before Tax ($ million)	Income After Tax ($ million)	Income After Tax as a Percent of Sales
1964	36,300	N/A	2,900	7.9
1965	40,100	N/A	3,200	7.9
1966	44,500	N/A	3,500	7.8
1967	47,500	N/A	3,260	6.9
1968	52,000	N/A	3,530	6.8
1969	55,500	N/A	3,590	6.5
1970	58,100	N/A	3,430	5.9
1971	62,020	6,700	3,778	6.1
1972	69,338	7,788	4,422	6.4
1973	83,581	9,978	5,686	6.8
1974	84,928	10,285	7,152	8.4
1975	88,168	9,668	6,703	7.6
1976	101,809	11,268	7,610	7.5
1977	113,389	11,806	8,047	7.1

Source: Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacturing Notification Requirements, (Cambridge, Mass.: 1978).

Exhibit C-20 indicates the sensitivity of cash inflow present values to changes in ROS. As might be expected, a change from four to 10 percent (a two-and-one-half times increase in profits) has a significant effect on PV and subsequently on the cumulative distribution plot as shown in Exhibit C-21. For example, changing the ROS from six percent to 10 percent changes the reduction in new chemical introductions from five percent to two percent in the base case. In Exhibit C-20 and Exhibit C-21, the base case discount rate (15 percent) has been used, and only ROS varied. The contribution from depreciation has not changed.

Sensitivity to Growth Rates

Ideally, the actual sales histories for each sample chemical should be used in the analysis. In lieu of this, the use of the generalized product life cycle sales concept is reasonable, as discussed earlier and shown again here in Exhibit C-22. This model can accurately predict the average growth and decline in sales during a product's life time, but it must follow the actual life cycle of the product, as the model's growth rate changes drastically over the life cycle. It is thus very sensitive to time and may, if applied without a reasonable understanding of the product and its markets, produce a misleading forecast.

EXHIBIT C-20

SENSITIVITY OF THE PRESENT VALUE OF CASH INFLOWS
TO CHANGES IN RETURN ON SALES (ROS)

(15% DISCOUNT RATE)

	Present Value ($)		
Chemical	4% ROS	6% ROS	10% ROS
1	2,100	3,151	5,251
2	8,057	12,085	20,141
3	10,909	16,363	27,272
4	18,217	27,325	45,542
5	18,705	28,058	46,763
6	20,024	30,036	50,060
7	22,671	34,006	56,677
8	31,577	47,366	78,943
9	42,841	64,262	107,103
10	47,037	70,555	117,592
11	76,191	114,287	190,478
12	298,329	447,493	745,822

EXHIBIT C-21

SENSITIVITY OF RESULTS TO CHANGES IN ROS

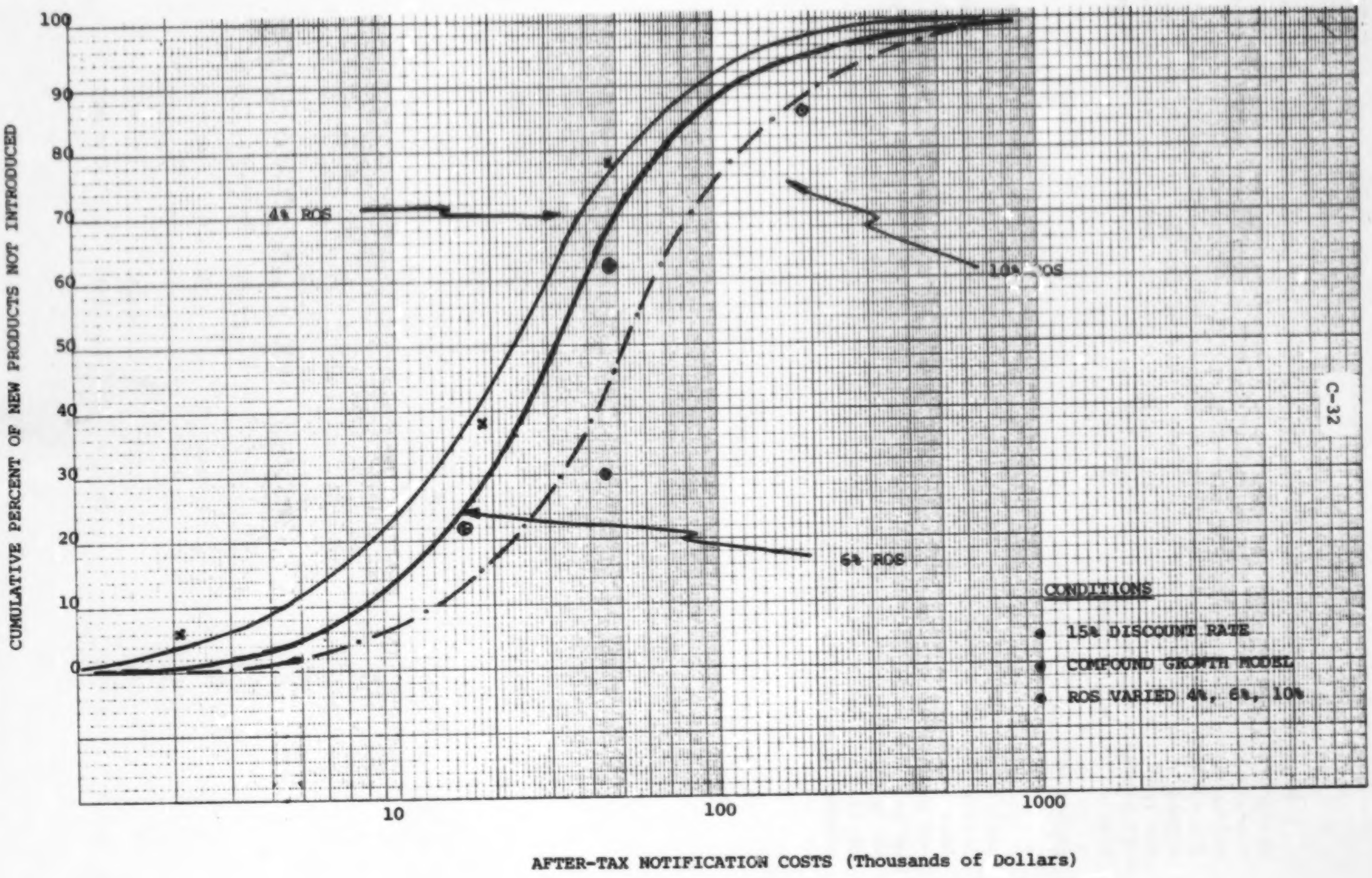
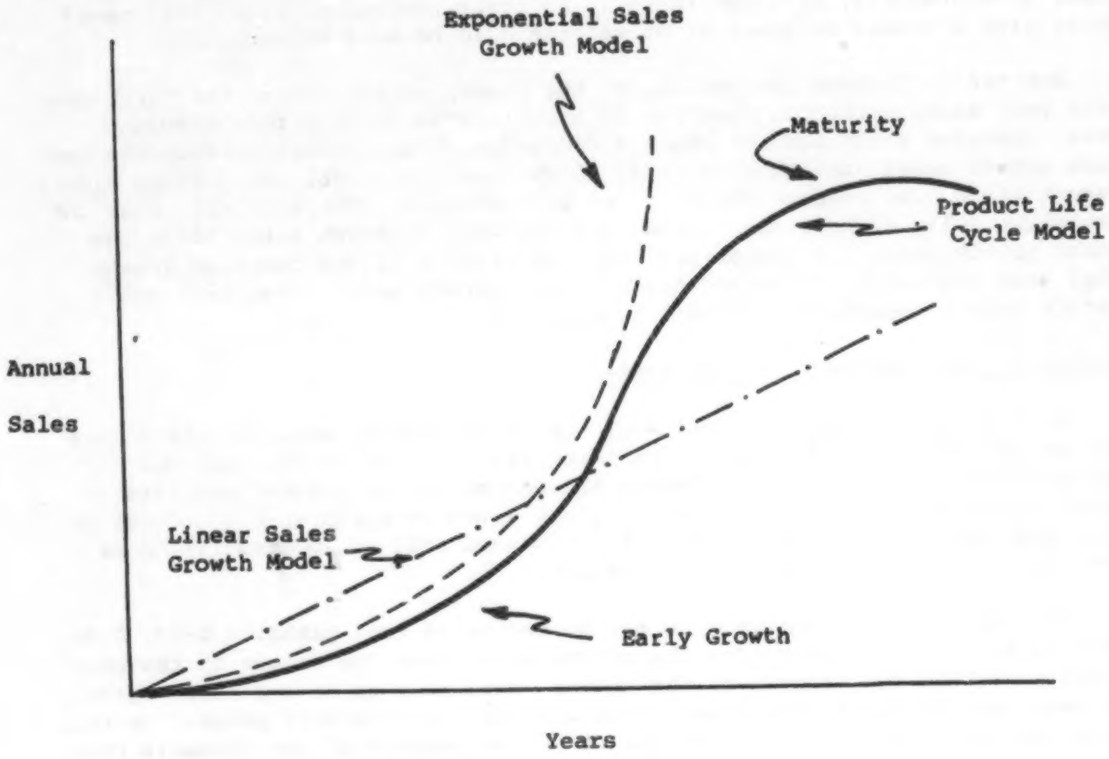


EXHIBIT C-22

PRODUCT LIFE CYCLE/EXPONENTIAL/LINEAR SALES GROWTH MODEL COMPARISON



As shown in Exhibit C-22, the embryonic and early growth phases have positive exponential growth, and thus can be closely modeled by a exponential (or compound) growth function. If the assumption is made that the maturity or late growth phase has not occurred then the use of an exponential model is appropriate. If the late growth phase is assumed to have occured, then a linear model might be less misleading. For these reasons, the sensitivity of the chemicals' PVs of cash inflows are being tested with both the compound and linear growth models, although there is no assurance which, if either, model should give a higher or lower PV or which should be more reasonable.

Exhibit C-23 shows the results of the linear model, giving the first and tenth year sales estimates, and PVs of cash inflows for the four discount rates, assuming a six percent ROS. A comparison with estimates using the compound growth model (see Exhibit C-14) shows that the linear model gives higher present values for returns for seven of 10 chemicals. Exhibit C-24 shows the cumulative sales distribution curves for the four discount rates using the linear growth model. A comparison with the results of the compound growth model (see Exhibit C-17) shows that a linear growth model assumption would predict lesser impacts at any notification cost.

Sensitivity to Changes in Notice Costs

At a minimum, a new chemical will not be introduced whenever the notice cost exceeds the present value of cash inflows. To the extent that our approximation of depreciation charges discounted to the present understates actual investment costs, the present values given in Exhibits C-16, C-20, or C-23, and the impact on new chemicals introduced will be underestimated by some unknown, but relatively small, amount.

The impact of any notice cost may be estimated from Exhibits C-17, C-21, and C-24 as follows: calculate the notice cost, find the amount on the horizontal axis that corresponds to the notice cost, move up to the sales curve, and read left to the vertical axis from the curve's intercept point. In this case, the number at that intercept point is the percent of new chemcals that will not be introduced.

EXHIBIT C-23

SENSITIVITY OF CASH INFLOW PV TO USE OF THE LINEAR GROWTH SALES MODEL[a]

			Present Value (discount rate)			
Chemical	First Year Sales ($K)	Tenth Year Sales ($K)	10%	15%	30%	45%
1	2.2	22.0	5,000	3,793	1,892	1,111
2	72.9[b]	30.4[b]	57,312	47,366	29,444	20,401
3	8.0	90.0	20,027	15,171	7,571	4,445
4	8.9	89.0	22,283	16,881	8,423	4,945
5	15.5	155.0	38,790	29,394	14,668	8,611
6	16.6	166.0	41,548	31,477	15,703	9,223
7	17.6	176.0	44,048	33,373	16,651	8,341
8	155.0[b]	18.9[b]	141,296	114,287	67,874	45,700
9	19.8	198.0	49,551	37,540	12,492	11,001
10	47.3	473.0	118,381	89,691	44,767	26,277
11	50.0	500.0	125,134	94,820	55,929	27,785
12	480.0	4,800.0	1,201,384	910,200	454,260	266,688

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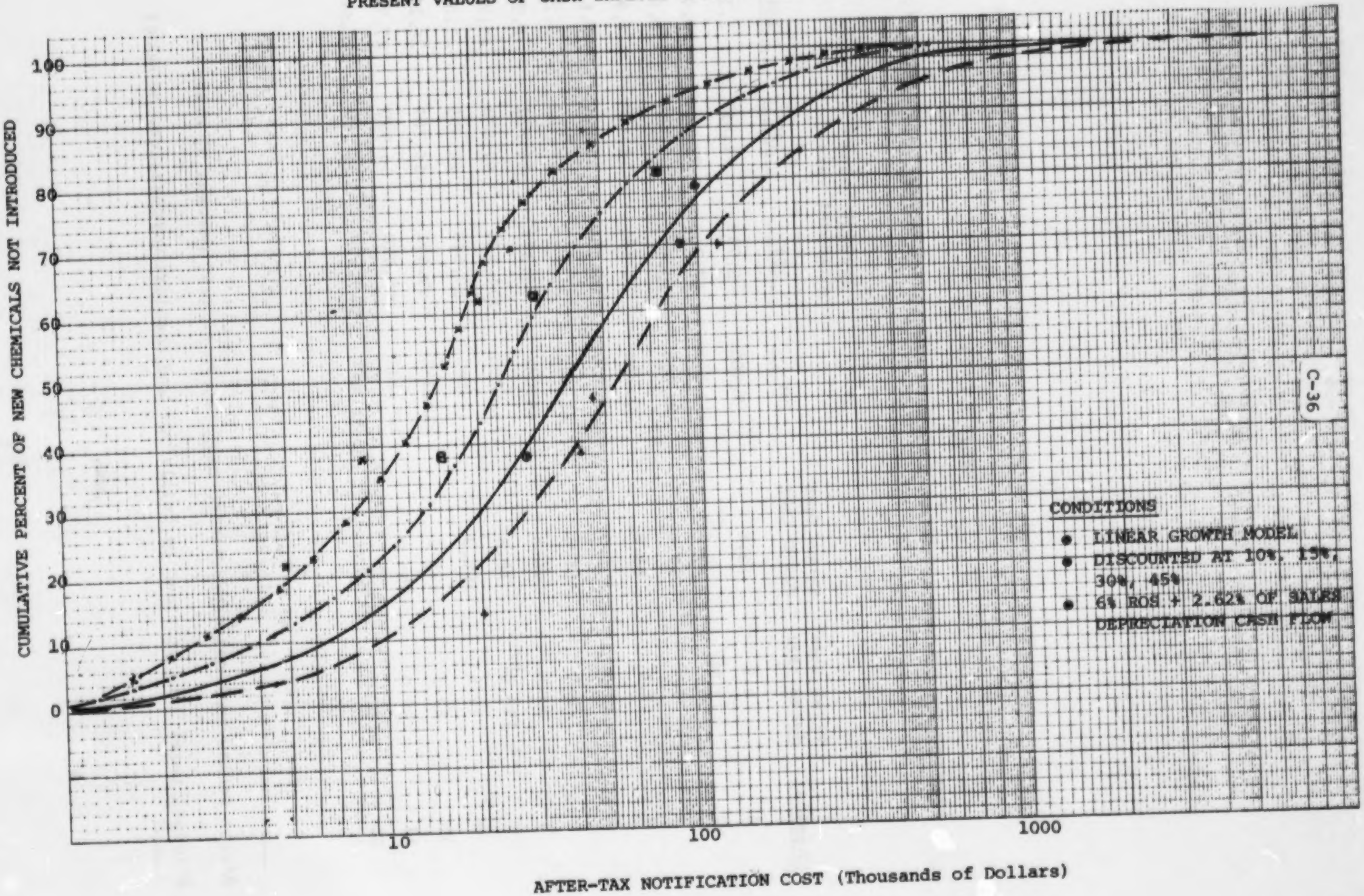
[a] Cash inflow includes depreciation cash return at 2.62 percent of sales.

[b] Actual sales data provided by Reilly Tar and Chemical Corporation, no model used.

EXHIBIT C-24

PRESENT VALUES OF CASH INFLOWS USING LINEAR GROWTH MODEL



SUPPLEMENT TO APPENDIX C

SALES DATA USED IN ECONOMIC ANALYSIS

This supplement contains the sales data generated for each chemical sample used in the analysis. Data on two of the chemicals were provided by the Reilly Tar and Chemical Company, as part of their public response to the reproposal (44 Federal Register 59764). For these two samples, sales volumes (in pounds) for the years 1967 through 1976 were converted into dollars by multiplying by the average price received during that year. The appropriate price and resultant sales value in dollars are shown in Exhibits C-33 and C-36. For these two chemicals, no sales growth model was used. For the remaining 10 samples, both linear and exponential (compound interest) model results are shown.

These tables do not include cash flows from depreciation. This cash flow, calculated as a percent of sales as discussed in the subsection Depreciation, can be found for any particular chemical and year by multiplying the value found in any appendix table by .0262 (2.62 percent). All calculations performed in the section Analysis of PMN Costs Impacts on New Chemical Introductions include depreciation cash flows.

Linear Model Data

As previously discussed, the linear model calculated sales in each year by dividing 1977 sales by the total years of sales. The resulting number was sales in Year 1, and each subsequent year simply added this number for total sales. Thus, if sales in year one were "X", sales in year two were 2X; year three, 3X; and so on. The values for the chemicals in the 10th year of sales are shown in Exhibit C-25.

Because the numbers of direct interest are the present value of sales and return on sales, only present values at the four discount rates (10 percent, 15 percent, 30 percent, and 45 percent) are shown for sales summed for 10 years. For the linear model, sales in any year can be derived from the non-discounted year 10 sales by dividing by the appropriate factor; thus, only 10th year sales estimates are given. The present values of the sum of 10 years of sales and net income after tax at four percent, six percent, and 10 percent return on sales (ROS) are shown as well.

Exponential (Compound Interest) Model Data

Data for the 10 chemical samples from the Arthur D. Little report as well as the Reilly Tar and Chemical Company data are shown in Exhibits C-26 through C-37. Each exhibit contains the present value of sales at each discount rate (10 percent, 15 percent, 30 percent, and 45 percent) for each year, the total 10 years present value of sales, and the returns for each ROS (four percent, six percent, and 10 percent). The growth rate, calculated as discussed in the subsection Sales Growth, is shown at the top of each table.

EXHIBIT C-25

LINEAR GROWTH MODEL (PRESENT VALUE SUMMED FOR TEN YEARS OF SALES)

($1000)

Chemical	ICF 10th Year Linear Growth Estimate	10% Discount			15% Discount			30% Discount			45% Discount		
		Return on Sales			Return on Sales			Return on Sales			Return on Sales		
		.04	.06	.10	.04	.06	.10	.04	.06	.10	.04	.06	.10
1	20	2.323	3.484	5.807	1.760	2.64	4.40	.8783	1.317	2.196	.5156	.7734	1.289
2	80	9.291	13.940	23.230	7.039	10.56	17.60	3.5130	5.270	8.783	2.0630	3.0940	5.156
3	89	10.340	15.510	25.840	7.831	11.75	19.58	3.9080	5.863	9.771	2.2950	3.4420	5.736
4	155	18.000	27.000	45.010	13.640	20.46	34.10	6.8070	10.210	17.020	3.9960	5.9940	9.990
5	166	19.280	28.920	48.200	14.610	21.91	36.52	7.2900	10.930	18.220	4.2800	6.4200	10.700
6	176	20.440	30.660	51.100	15.490	23.23	38.72	7.7290	11.590	19.320	4.5380	6.806	11.340
7	198	23.000	34.490	57.490	17.420	26.13	43.56	8.6950	13.040	21.740	5.1050	7.657	12.760
8	500	58.080	87.100	145.180	44.000	66.00	110.00	21.9580	32.930	54.900	12.8900	19.340	32.230
9	473	54.940	82.400	137.340	41.620	62.43	104.05	20.7700	31.160	51.930	12.1900	18.290	30.490
10	4,800	557.490	836.230	1,393.700	422.370	633.55	1,055.91	210.7900	316.190	526.980	123.7500	185.630	309.380

Source: ICF Estimates.

EXHIBIT C-26

PRESENT VALUE OF CHEMICAL #1 SALES OVER TEN YEARS

(growth rate = 24.36 percent per year)

	Discount Rate			
End of Year	10%	15%	30%	45%
1	2.180	2.180	2.180	2.18
2	2.456	2.357	2.085	1.870
3	2.786	2.549	1.995	1.604
4	3.150	2.757	1.908	1.375
5	3.561	2.981	1.826	1.180
6	4.026	3.224	1.746	1.012
7	4.552	3.486	1.671	.8676
8	5.146	3.770	1.598	.7441
9	5.818	4.077	1.529	.6382
10	6.577	4.409	1.462	.5474
11	7.436	4.767	1.399	.4694
Total	47.700	36.560	19.400	12.4900
4% ROS	1.908	1.462	.776	.4995
6% ROS	2.862	2.193	1.164	.7492
10% ROS	4.770	3.656	1.940	1.2490

EXHIBIT C-27

PRESENT VALUE OF CHEMICAL #2 SALES OVER TEN YEARS

(growth rate = 23.83 percent per year)

	Discount Rate			
End of Year	10%	15%	30%	45%
1	8.920	8.920	8.920	8.920
2	10.040	9.605	8.497	7.618
3	11.300	10.340	8.093	6.505
4	12.730	11.140	7.709	5.556
5	14.330	11.990	7.343	4.745
6	16.130	12.910	6.995	4.052
7	18.150	132.900	6.663	3.450
8	20.440	14.970	6.347	2.955
9	23.010	16.120	6.045	2.524
10	25.900	17.360	5.758	2.155
11	29.150	18.690	5.485	1.841
Total	190.090	145.950	77.860	50.330
4% ROS	7.604	5.838	3.114	2.013
6% ROS	11.410	8.757	4.671	3.020
10% ROS	19.010	14.500	7.786	5.033

EXHIBIT C-28

PRESENT VALUE OF CHEMICAL #3 SALES OVER TEN YEARS

(growth rate = 14.60 percent per year)

End of Year	Discount Rate 10%	15%	30%	45%
1	17.560	17.560	17.560	17.560
2	18.290	17.500	15.480	13.880
3	19.060	17.440	13.650	10.970
4	19.860	17.380	12.030	8.669
5	20.690	17.320	10.600	6.852
6	21.550	17.260	9.348	5.415
7	22.450	17.200	8.241	4.280
8	23.390	17.140	7.265	3.383
9	24.370	17.080	6.404	2.673
10	25.390	17.020	5.645	2.113
11	26.450	16.960	4.977	1.670
Total	239.060	189.830	111.200	77.460
4% ROS	9.563	7.593	4.448	3.098
6% ROS	14.340	11.390	6.672	4.648
10% ROS	23.900	18.980	11.120	7.746

EXHIBIT C-29

PRESENT VALUE OF CHEMICAL #4 SALES OVER TEN YEARS

(growth rate = 27.10 percent per year)

	Discount Rate			
End of Year	10%	15%	30%	45%
1	16.630	16.63	16.630	16.630
2	19.220	18.38	16.260	14.580
3	22.202	20.31	15.900	12.780
4	25.650	22.45	15.540	11.200
5	29.640	24.81	15.200	9.818
6	34.250	27.42	14.860	8.606
7	39.570	30.31	14.520	7.543
8	45.730	33.50	14.200	6.612
9	52.830	37.02	13.880	5.796
10	61.050	40.92	13.570	5.080
11	70.540	45.22	13.270	4.453
Total	417.310	316.99	163.830	103.090
4% ROS	16.690	12.68	6.553	4.124
6% ROS	25.040	19.02	9.830	6.186
10% ROS	41.730	31.70	16.380	10.310

EXHIBIT C-30

PRESENT VALUE OF CHEMICAL #5 SALES OVER TEN YEARS

(growth rate = 29.15 percent per year)

	Discount Rate			
End of Year	10%	15%	30%	45%
1	15.50	15.50	15.500	15.500
2	18.20	17.41	15.400	13.810
3	21.37	19.55	15.300	12.300
4	25.09	21.95	15.200	10.950
5	29.45	24.66	15.100	9.755
6	34.58	27.69	15.000	8.689
7	40.60	31.10	14.900	7.739
8	47.67	34.92	14.800	6.893
9	55.97	39.22	14.710	6.140
10	65.71	44.05	14.610	5.469
11	77.15	49.46	14.520	4.871
Total	431.29	325.50	165.030	102.110
4% ROS	17.25	13.02	6.601	4.084
6% ROS	25.88	19.53	9.902	6.127
10% ROS	43.13	32.55	165.030	10.210

EXHIBIT C-31

PRESENT VALUE OF CHEMICAL #6 SALES OVER TEN YEARS

(growth rate = 44.22 percent per year)

	Discount Rate			
End of Year	10%	15%	30%	45%
1	8.00	8.00	8.000	8.000
2	10.49	10.03	8.875	7.957
3	13.75	12.58	9.846	7.914
4	18.03	15.78	10.920	7.872
5	23.64	19.79	12.120	7.829
6	30.99	24.82	13.440	7.787
7	40.63	31.12	14.910	7.745
8	53.27	39.03	16.540	7.704
9	69.85	48.95	18.350	7.662
10	91.58	61.38	20.360	7.621
11	120.07	76.98	22.590	7.580
Total	480.30	348.45	155.970	85.67
4% ROS	19.21	13.94	6.239	3.427
6% ROS	28.82	20.91	9.358	5.140
10% ROS	48.03	34.85	15.600	8.567

EXHIBIT C-32

PRESENT VALUE OF CHEMICAL #7 SALES OVER TEN YEARS

(growth rate = 31.67 percent per year)

	Discount Rate			
End of Year	10%	15%	30%	45%
1	16.66	16.66	16.660	16.660
2	19.94	19.07	16.870	15.130
3	23.87	21.84	17.090	13.740
4	28.57	25.01	17.310	12.470
5	34.20	28.63	17.530	11.330
6	40.94	32.78	17.760	10.290
7	49.00	37.53	17.990	9.340
8	58.66	42.97	18.220	8.482
9	70.21	49.20	18.450	7.702
10	84.05	56.33	18.690	6.994
11	100.60	64.50	18.930	6.351
Total	526.72	394.54	195.500	118.490
4% ROS	21.07	15.78	7.820	4.739
6% ROS	31.60	23.67	11.730	7.109
10% ROS	52.67	39.45	19.550	11.850

EXHIBIT C-33

PRESENT VALUE OF REILLY CHEMICAL #2 OVER TEN YEARS

(Chemical #8 in text of this section.)

				Present Value (discount rate)			
Year	Sales (lbs.)	Price/lb.	Value	10%	15%	30%	45%
1967	2,700	$27.00	72,900	66,273	63,391	56,077	50,276
1968	2,500	35.00	87,500	72,314	66,163	51,775	41,617
1969	16,800	11.40	191,520	143,892	125,928	87,173	62,822
1970	22,600	9.60	216,960	148,187	124,048	75,964	49,080
1971	1,000	43.00	43,000	26,700	21,379	11,581	6,709
1972	400	66.00	26,400	14,902	11,413	5,469	2,841
1973	11,000	13.70	150,700	77,333	56,654	14,017	11,182
1974	22,000	10.00	220,000	102,632	71,918	26,970	11,258
1975	5	760.00	3,800	1,612	1,080	358	134
1976	40	760.00	30,400	11,721	7,514	2,205	740
		Total:		665,566	549,488	341,589	236,659
	Total x .04 ROS			26,622	21,980	13,664	9,466
	Total x .06 ROS			39,934	32,969	20,495	14,200
	Total x .10 ROS			66,557	54,949	34,159	23,666

Source: Reilly Tar & Chemical Company and ICF Estimates.

EXHIBIT C-34

PRESENT VALUE OF CHEMICAL #9 SALES OVER TEN YEARS

(growth rate = 21.81 percent per year)

	Discount Rate			
End of Year	10%	15%	30%	45%
1	50.00	50.00	50.00	50.000
2	55.37	52.96	46.85	42.000
3	61.31	56.10	43.90	35.290
4	67.90	59.42	41.13	29.640
5	75.18	62.94	38.54	24.900
6	83.26	66.66	36.11	20.920
7	92.20	70.61	33.84	17.570
8	102.09	74.79	31.71	14.760
9	113.06	79.22	29.71	12.400
10	125.19	83.91	27.84	10.420
11	138.63	88.88	26.08	8.752
Total	914.19	745.51	405.71	266.660
4% ROS	36.57	29.82	16.23	10.670
6% ROS	54.85	44.73	24.34	16.000
10% ROS	91.42	74.55	40.57	26.670

EXHIBIT C-35

PRESENT VALUE OF CHEMICAL #10 SALES OVER TEN YEARS

(growth rate = 43.15 percent per year)

End of Year	Discount Rate 10%	15%	30%	45%
1	19.80	19.80	19.80	19.800
2	25.77	24.65	21.80	19.550
3	33.53	30.68	24.01	19.300
4	43.64	38.19	26.44	19.050
5	56.79	47.54	29.11	18.810
6	73.90	59.17	32.06	18.570
7	96.17	73.66	35.30	18.330
8	125.16	91.69	38.87	18.100
9	162.88	114.13	42.80	17.870
10	211.96	142.07	47.13	17.640
11	275.84	176.85	51.90	17.410
Total	1,125.43	818.43	369.21	204.420
4% ROS	45.02	32.74	14.77	8.177
6% ROS	67.53	49.11	22.15	12.270
10% ROS	112.54	81.84	36.92	20.440

EXHIBIT C-36

PRESENT VALUE OF REILLY #7 CHEMICAL OVER TEN YEARS

(Chemical #11 in text of this section.)

Year	Sales (lbs.)	Price/lb.	Value	Present Value (discount rate) 10%	15%	30%	45%
1967	11,400	$13.60	155,040	140,945	134,817	119,262	106,924
1968	26,600	9.20	244,720	202,248	185,043	144,805	116,395
1969	32,400	8.60	278,640	209,346	183,210	126,827	91,399
1970	60,200	6.40	385,280	263,151	220,285	134,897	87,157
1971	84,500	3.30	278,850	173,144	138,638	75,102	43,504
1972	75,800	5.20	394,160	222,493	170,406	81,661	42,410
1973	113,000	13.70	150,700	77,333	56,654	14,017	11,182
1974	186,000	1.30	241,800	112,801	79,045	29,642	12,374
1975	53,000	6.90	365,700	155,093	103,955	34,485	12,836
1976	135,000	1.40	189,000	72,868	46,718	13,710	4,600
		Total:		1,639,069	1,325,838	787,404	530,176
	Total x .04 ROS			65,562	53,034	31,496	21,207
	Total x .06 ROS			98,344	79,550	47,244	31,810
	Total x .10 ROS			163,907	132,584	78,740	53,017

Source: Reilly Tar & Chemical Company and ICF Estimates.

EXHIBIT C-37

PRESENT VALUE OF CHEMICAL #12 SALES OVER TEN YEARS

(growth rate = 14.61 percent per year)

End of Year	Discount Rate 10%	15%	30%	45%
1	480.00	480.00	480.00	480.00
2	500.12	478.37	423.18	379.40
3	521.08	476.75	373.08	299.88
4	542.91	475.13	328.91	237.03
5	565.67	473.52	289.97	187.35
6	589.37	471.92	255.64	148.09
7	614.07	470.32	225.38	117.05
8	639.81	468.72	198.70	92.52
9	666.62	467.13	175.18	73.13
10	694.56	465.55	154.44	57.80
11	723.67	463.97	136.15	45.69
Total	6,537.88	5,191.37	3,040.63	2,117.93
4% ROS	261.52	207.65	121.63	84.72
6% ROS	392.27	311.48	182.44	127.08
10% ROS	653.79	519.14	304.06	211.79

APPENDIX D

DISCUSSION OF THE ECONOMIC BURDEN OF SECTION 5 NOTICE REQUIREMENTS ON EPA AND SOCIETY

APPENDIX D

INTRODUCTION

The section 5 notice (hereafter notice) policy may impose economic burdens on three principal actors:

- the chemical industry;
- the EPA; and
- society (i.e., the intended beneficiaries of TSCA--including public and special interest groups).

The purpose of this document is to identify the potential costs to EPA and to society associated with these notice policy issues:[1]

- Processor Reporting Rule;
- Importer Definition Options;
- Importer Contact of Foreign Manufacturers/Suppliers;
- Exporter Options;
- Customer Contact;
- Insufficient Submissions;
- Supplemental Reporting; and
- Confidentiality Options.

These issues are examined individually.[2] The criteria used to identify the costs to EPA and society vary from issue to issue depending on the options.

This paper is designed to assist EPA in making better decisions in each case by constructing a framework from which to evaluate the proposed rule and its alternatives.

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[1] Costs imposed on the chemical industry have been assessed. See "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II-Issue Papers (Washington, D.C.: ICF Incorporated, September 1980). This Appendix should be read in parallel with Part II.

[2] The Possession or Control issue is not discussed here.

Because many of the costs associated with these issues do not lend themselves easily to quantification, the major outcome of this discussion is an ordinal ranking of options by expected economic costs to EPA and society.

THE PROCESSOR REPORTING RULE

Under the joint statutory authority of TSCA sections 5(a)(1) and 5(a)(2), EPA has proposed to require the person[3] who first processes an exempt, non-inventoried substance for a nonexempt purpose to submit a section 5 notice. Without such a rule, persons could process for a TSCA commercial purpose an exempt substance which was not on the Inventory and which was never reviewed for toxic effects.

Options

For the purposes of this discussion, EPA specified the following options for the processor reporting rule:

Option 1: Proposed Processor Reporting Rule with section 5 notice similar to the October 16 form proposed for manufacturers.

Option 2: January 10 Proposal--Manufacturer Reporting requirement.

Option 3: No reporting for commercial processing of exempt substances.

Option 4: Section 8 Processor Notification.

Option 5: Processor rule as proposed with exemption for one-time processing.

Option 6: Combination of section 5 and section 8(a) notices.

Option 7: Section 5 notification under minimum guidance option.

Each of these options is evaluated below according to the costs it imposes on EPA and on society.[4]

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[3] For purposes of this report, "person" can be an individual or a corporate entity.

[4] Thorough descriptions of these options are contained in: "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II - Issue Papers, Chapter 8--Processor Reporting (Washington, D.C.: ICF Incorporated, September 1980).

EPA Costs

A portion of the economic costs of a processor rule will fall on EPA in the form of notice reviews and expenditures related to requests for supplemental information.

Under the proposed processor rule, costs to the Agency would be identical to those incurred for manufacturers and importers under the premanufacturing notification proposal. The major difference between the processor rule and the January 10 and October 16 proposals is coverage; with a processor notice rule, EPA would have additional notices to review. However, the processor rule as proposed with an exemption for one-time processing would reduce the number of notices submitted for review.

A section 8 rule would represent less of a burden on EPA than a section 5 processor rule to the extent that a section 8 notice requires less information. The review process is made complicated when a section 5 rule is proposed in combination with a section 8 rule, but the marginal cost to EPA associated with such a combination is unclear. In addition to review costs, a combined rule would impose other significant costs on EPA in the form of identifying chemical categories that would be subject to section 5 notices.

Finally, the "no reporting" alternative would not impose any costs on EPA. Exhibit D-1 presents a ranking of the options by two types of costs to EPA: administrative and insufficient information. A "1" corresponds to the least costly option.

Administrative Costs. The first column of Exhibit D-1 ranks the options by the per-notice administrative cost of review. The amount of information requested in the notice was the key factor in deciding which option would require longer and more careful review by EPA. Thus, because separate processors would not submit information under Options 2 and 3, these options were ranked as the least costly.

Section 8 notices could request less information than section 5 notices, and EPA would presumably require less time to review them. Thus, Option 4 was ranked as the second least costly alternative. A notice submitted under the minimum guidance option may contain more information than a section 8 notice, and thus Option 7 ranked higher than Option 4 in review costs.

EPA would have the most information to review under any of the options requiring a section 5 notification. Thus, costs of review are highest when a section 5 notice is submitted.

Options 5 and 6 may rank similarly to Option 1 or Option 4, depending on whether a section 5 or a section 8 notice applies.

Insufficient Information Costs. The second column of Exhibit D-1 ranks the options in terms of information submitted to EPA. If a notice submitted under an option does not provide sufficient information for EPA to make an

EXHIBIT D-1

RANKING OF PROCESSOR NOTIFICATION OPTIONS BY COSTS TO EPA

Option / Cost	Review	Insufficient Information to Support Regulation
1. Proposed Processor Notice Rule	3	1
2. January 10 Proposal	0	3
3. No Reporting	0	3
4. Section 8 Notice	1	2
5. Processor Rule With Exemption	1 or 3	1 or 2
6. Combined Section 5 and Section 8 Notice	1 or 3	1 or 2
7. Minimum Guidance Option	2	1

A "1" indicates the least costly alternative.

optimum decision, then that represents a cost to the extent that there may exist more effective ways for the Agency to carry out its statutory responsibilities.

On the other hand, information requested under another option may help the Agency make a more qualified decision on how to regulate the substance in question. In Exhibit D-1, a rank of "1" indicates that of the options considered, EPA will have the best available information on which to base its decisions. A higher rank means that EPA will have less information on which to base its decision. Because EPA would receive no information under Option 3, the cost of insufficient information is highest here relative to the other options.

Society Costs

Promulgation of a processor notice rule may impose costs on society in the form of foregone chemicals and time delays in being able to use processed substances. These costs will equal the corresponding costs under the premanufacturing notification rule as proposed on January 10 and reproposed on October 16. Although these society costs may be significant, of greater importance is the tradeoff encountered by society for different levels of protection from toxic substances.

The tradeoff varies across alternative processor rules. The least stringent alternative (no reporting for commercial processing of exempt substances) affords the least amount of protection. In other words, without any mechanism for reviewing exempt substances prior to nonexempt commercial processing, the probability of a toxic substance (i.e., one that may present an "unreasonable risk of injury to health or the environment") entering commerce is maximized.

The probability of an "unreasonably risky" toxic substance entering commerce is decreased when substances undergo a review of toxicity prior to processing. In options that require notice submission (i.e., Options 1, 5, 7, and to an extent 2 and 6), that probability presumably is further diminished.

Exhibit D-2 presents a ranking of processor notification options by costs to society in terms of foregone chemicals, time delays, and unreasonable risks.

Foregone Chemicals and Time Delay Costs. The January 10 proposal and the option of no reporting received the lowest rank with respect to foregone chemicals and time delays for several reasons. First, the risk of an adverse determination would be absent because no separate processor notice would be submitted. The absence of such a risk would keep a person's decision to process unchanged; thus, society would not have to forego the use of any processed chemicals. Secondly, because no separate processor notice is submitted under either alternative, delays in being able to use the substances would be nonexistent. Both proposals rank high in terms of exposure risks for these reasons. Because the January 10 proposal contains provisions for reviewing a few processed substances, it ranked lower in terms of exposure risks than the option of no reporting.

EXHIBIT D-2

RANKING OF PROCESSOR NOTIFICATION OPTIONS BY COST TO SOCIETY

Option \ Cost	Foregone Chemicals	Time Delays	Unreasonable Risks
1. Proposed Processor Notice Rule	3	3	1
2. January 10 Proposal	1	1	6
3. No Reporting	1	1	6
4. Section 8 Notice	2	2	4
5. Processor Rule With Exemption	2 or 3	2 or 3	2
6. Combined Section 5 and Section 8 Notice	2 or 4	2 or 3	3
7. Minimum Guidance Option	3	3	1

A "1" indicates the least costly alternative.

The degree and extent of coverage under each option were used to rank the remaining options. For example, a section 8 notice covers fewer substances and requires less information than a section 5 notice. Thus, it would result in fewer foregone chemicals and shorter delays in processing. Delays and chemicals foregone under Option 5 (the processor rule with an exemption for one-time processing) depend on whether a section 5 or a section 8 notice is submitted. The same is true for Option 6.

Costs of Unreasonable Risks. Under each option, coverage and the type of information submitted to support regulation was used to rank the options in terms of unreasonable health and safety risks. Unreasonable risks are a function of exposure and toxicity. When coverage is widest, EPA has a chance to control a broader array of exposures. When valuable information to support regulation is submitted, EPA has a chance to determine whether the chemical's toxicity presents an unreasonable risk. Without information on toxicity, EPA cannot make a knowledgeable decision on whether or not to exercise its regulatory authority, and society may face unnecessary and unreasonable risks.

The proposed rule and the minimum guidance option would present fewer unreasonable risks among the options because they cover all nonexempt commercial processing and because available health and safety studies may be submitted. EPA would thus be able to make a more qualified decision on whether or not to take regulatory actions, and the amount of unreasonable risk to society is minimized.

Under the option of no reporting, unreasonable risks may be higher because EPA would have little information on which to base its regulatory decisions.

IMPORTERS

Under section 720.10(a)(2) of the January 10, 1979 proposed rules, "any person who intends to import" a new chemical substance is required to submit notification to EPA. Because of the variety of participants in importing and the technical nature of some of the information required in the notice, EPA is considering the question of which parties should be responsible or required to submit notification for imported new chemical substances.

Options

We have evaluated five alternatives for designating persons responsible for submission of section 5 notification on imported new chemical substances:[5]

Option 1: Define importer as the consignee.

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[5] These options are described more completely in: "Economic Impact Analysis of Proposed Section 5 Notice Requirements", Part II - Issue Papers, Chapter 3 - Definition of Importers (Washington, D.C.: ICF Incorporated, September 1980).

Option 2: Define importer as consignee, and impose upon him an obligation to obtain the information required by the rules and forms from other persons.

Option 3: Use January 10 proposal importer definition.

Option 4: Define importer as "the person who imports, or knowingly causes to be imported a chemical substance."

Option 5: Clarify January 10th proposal by changing definitions so that principal importer must submit section 5 notice.

Each of these options is evaluated on the basis of costs to EPA and society. It is assumed that the notification form submitted for all five options is the October 16th reproposed form.

EPA Costs

Costs incurred by EPA include (1) administrative costs of reviewing notices, and (2) expenditures related to requests for supplemental information.

Administrative Costs. The likelihood of submission of notices to EPA under each option is used as the measure of administrative costs. Since the same form will be submitted under each option, the administrative costs to EPA depend on how many forms actually are submitted; the more notices submitted, the more reviewing by EPA will be required.

The definition of importers under Option 5 is intended to reach a single individual. However, the parties involved will face some uncertainty as to who will submit notification in different types of import transactions unless these circumstances are defined in great detail.

Under Options 3 and 4, a single person with responsibility for submission is not identified. Since no one party has primary responsibility, it is more likely that a new chemical will be imported without any notification being submitted. In addition, these alternatives burden the parties involved with negotiating an agreement on who should submit notification. This increases the uncertainty faced by the parties, and thus decreases the likelihood of submission of a notice.

Exhibit D-3 shows the relative administrative costs to EPA under each option. If all importers comply with the law the administrative costs would be identical across all options.

Supplemental Information Costs. To measure the amount of resources EPA must expend requesting supplemental information, we assume that the more technical knowledge the submitter has, the better will be the quality of information submitted. Presumably, EPA will devote more resources requesting

EXHIBIT D-3

THE RELATIVE COSTS OF IMPORTER DEFINITION OPTIONS

Options \ Costs	EPA Cost 1 (Administrative)	EPA Cost 2 (Supplemental Information)	Society Cost
1. Importer Defined as Consignee	3	3	3
2. Importer as Consignee With Obligation To Obtain Information From Others	3	2	2
3. January 10 Proposal	1	2	2
4. Importer as "Person Who Imports Or Knowingly Causes To Be Imported A Chemical Substance"	1	2	2
5. Principal Importer Must Submit Section 5 Notice	2	1	1

A "1" indicates the least costly alternative.

supplemental information when the quality or quantity of information submitted in the notice is poor.

Some of the options evaluated here do not specify how many people will be involved in the notification process, nor whom these persons will be. It is difficult, therefore, to assess the level of technical knowledge a submitter has, and then to estimate the quality of information submitted. Under any of the options, the behavior of the parties involved cannot be predicted with certainty. For example, under Option 1, the submitter is the consignee of the imported chemical, and may be a retailer or a broker. Retailers who intend to process, use or distribute the imported chemical themselves, presumably would have the technical knowledge to submit a section 5 notice. On the other hand, brokers rarely would be aware or able to determine that chemical shipments in a consignment are "new". As a result of this uncertainty as to the level of technical knowledge of the consignee, we will evaluate each option according to the opportunity for the most knowledgeable person to submit notification.

As discussed above, under Option 1, the consignee may not be the most knowledgeable person (if the consignee is a broker) to submit a section 5 notice. A broker does not have the technical knowledge to adequately submit the notification form. By relying on brokers to submit notification under Option 1, EPA would be limiting itself to the minimum of information available; EPA would be most likely to require supplemental information under Option 1.

Option 2 notices would contain better information than Option 1 notices. The submitter of Option 2 notices is required to obtain information from other persons, including identifiable future users and processors of the chemical. These other persons would be expected to possess some technical knowledge, and improve the quality of information available to EPA.

Option 3 requires each of the parties included in the definition of importer to be responsible for submission. If all the parties with technical knowledge are responsible for submitting a notice to EPA, the quality of information would be high. However, there is no assurance provided by this regulation that the most knowledgeable party would agree, or could be persuaded, to submit a Section 5 notification.

The Option 4 definition of importer requires the most knowledgeable person to submit notification. In some cases, it might prove difficult for both the Agency and the parties involved to identify the most knowledgeable person.

Finally, Option 5 is designed to get the most knowledgeable person to submit notification. Thus, Option 5 notices may contain better information than the other options; the necessity of EPA requesting supplemental information will be minimized under Option 5. Exhibit D-3 shows the relative supplemental information costs of the five importer options.

Society Costs

Costs to society are incurred when the public is not protected from toxic substances. The probability of an "unreasonably risky" toxic substance entering commerce is decreased when substances undergo a review for toxicity prior to processing. In the case of imported chemicals, the factors determining their review include: (1) whether or not a section 5 notice is submitted, and (2) the quality of information submitted. Presumably, society is well protected (and hence costs to society are low) when a section 5 notice is submitted that has been filled out by the most knowledgeable person involved with importing the chemical.

According to these criteria, Option 5 affords the greatest protection to society (and the least cost in terms of unreasonable risk). Under Option 5, the information included in the notice will be high in quality, and only one person is responsible for submitting the notice.

It is difficult to predict the relative consequences of choosing among Options 2, 3, and 4. They are ranked equivalently in terms of society costs. Option 1 notices will provide the lowest quality information of all the options.

IMPORTER CONTACT OF FOREIGN MANUFACTURERS/SUPPLIERS

This issue concerns obtaining information from foreign manufacturers and suppliers about new chemical substances being imported into the United States.

Options

The following four alternatives are evaluated according to the costs they impose on EPA and society:[6]

Option 1: mandatory contact and the Foreign Manufacturers/Suppliers Form outlined in the January 10 proposal;

Option 2: mandatory contact and a Foreign Manufacturers/Suppliers Form revised to be consistent with the forms in the October 16 reproposal;

Option 3: mandatory contact and the request for only health and environmental effects data and risk assessments from foreign manufacturers/suppliers; and

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[6] A separate document contains thorough descriptions of these options: "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II - Issue Papers, Chapter 4-Importer Contact of Foreign Manufacturers/Suppliers (Washington, D.C.: ICF Incorporated, September 1980).

Option 4: no mandatory contact by importer.

An assessment of the costs to EPA and society imposed by any of the four options is made difficult by the fact that cooperation on the part of foreign manufacturers/suppliers is voluntary. An assessment of the relative costs of each option must depend on some assumptions about the behavior of industry parties. It is difficult to predict, for example, whether a foreign manufacturer will submit more information if asked for it, or whether the more onerous request will discourage submission of some or possibly any information. Currently, many foreign manufacturers must submit information to their own governments which is equivalent or similar to that which would be required under the proposed regulations.

EPA Costs

We examine EPA's costs in terms of the ease of administration of various options. Ease of administration will be high when the foreign manufacturer/supplier form is consistent with the domestic manufacturer form. EPA then will have only one notice format to review. Assuming the domestic manufacturer form will be the October 16 proposal, Option 2 will be the least costly to EPA.

Option 3 is ranked less costly to EPA than Options 1 or 2, since the amount of information EPA must review is less under Option 3; the foreign manufacturers/suppliers form outlined in the January 10 proposal (Option 1) requests more information than that requested in Options 2 or 3.

Finally, under Option 4, a lack of adequate information hinders EPA's administration of the program. Mandatory contact by the importer is of practical benefit to EPA as a first step in obtaining necessary information. Because EPA cannot forego contact with the foreign manufacturer, Option 4 is most costly to the Agency. Exhibit D-4 displays these relative costs to EPA.

Society Costs

Costs to society are assessed on the basis of how much information EPA has available. A more informed decision by EPA, presumably, will protect society to the greatest degree.

EXHIBIT D-4

RELATIVE COSTS OF IMPORTER CONTACT OF FOREIGN MANUFACTURERS/SUPPLIERS

Costs Options	EPA Cost (Ease of Administration)	Society Cost (Risks)
1. January 10 Proposal	3	1
2. October 16 Proposal	2	2
3. Only Health and Environmental Effects Data and Risk Assessment	1	3
4. No Mandatory Contract	4	4

A "1" indicates the least costly alternative.

The amount of information submitted to EPA is highest under Option 1. The January 10 proposal includes several questions which are omitted in the October 16 reproposal. The other three Options, 2, 3, and 4, provide EPA with successively less information, and are successively more costly to society. Exhibit D-4 shows the progression from the least to the most costly option.

EXPORTERS

This issue pertains to the manufacture in the U.S. of new chemicals solely for the purpose of export abroad. EPA is concerned about whether unreasonable risk is posed by these new chemicals during manufacture and transport in the U.S.

Options

We have evaluated three alternatives concerning new chemicals manufactured solely for export:[7]

Option 1: Section 5 Notice.

Option 2: Section 8(a) Notice.

Option 3: No Notice.

Each of these options is evaluated on the basis of costs to EPA and society.

EPA Costs

The criterion used to assess EPA costs is the amount of information submitted to EPA under each option.

Both Options 1 and 2 would allow EPA to require supplemental reporting of information on a new chemical substance. The costs associated with this possibility would be the same under both options. Option 3 has no supplementary reporting costs.

The small business exemption under Option 2 proposes to exempt exporters with total annual sales of less than $1 million from reporting requirements. It is difficult, however, to estimate precisely how many firms will be exempted.

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[7] These options are described more completely in: "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II - Issue Papers, Chapter 5-Exporters (Washington, D.C.: ICF Incorporated, September 1980).

Option 3 is ranked as the least costly to EPA. Under Option 3, exporters are exempt from any reporting requirements for new chemicals manufactured solely for export. Thus, EPA will not incur any costs of reviewing notices for exporters. These rankings are summarized in Exhibit D-5.

Society Costs

The criterion used to assess society costs is the degree to which society is exposed to unreasonable risks under the various options. The more (quantity and quality) information available to EPA, the more knowledgeable a decision the Agency can make. In this way, society has the most protection from unreasonable risks.

Under the option of no reporting--Option 3--unreasonable risks posed to society may be higher because EPA will have no reported information about new chemicals manufactured solely for export.

Option 1 entails the widest coverage of exporters, differing from Option 2 in that Option 2 includes a small business exemption. To the extent that action under section 5 is more likely than action under other sections of TSCA, Option 1 offers EPA more authority to take action against new chemicals once notice has been submitted. Thus, Option 1 is ranked as the least costly alternative to society. For a summary of these rankings, see Exhibit D-5.

CUSTOMER CONTACT

To fully evaluate the environmental risks associated with the introduction of any new chemical, EPA may find it necessary to obtain information from those who purchase the chemical. The types of information sought would include worker exposure during processing, environmental release, disposal, and use by the general population.

Options

In this paper, we will assess the relative costs to EPA and to society of these options for customer contact:

Option 1: January 10 Proposal--Submitter must contact all customers in writing.

Option 2: October 16 Proposal--Submitter must contact all customers in writing who have made a firm commitment to purchase the substance.

Option 3: Provision of Estimated Number of Customers.

Option 4: Provision of Potential Customer List.

Option 5: Elimination of All Customer Contact Provisions.

EXHIBIT D-5

THE RELATIVE COSTS OF EXPORTER OPTIONS

Option / Cost	EPA Cost (Administrative)	Supplemental Costs	Society Cost (Risks)
1. Section 5 Notice	1	1	1
2. Section 8(a) Notice	1	1	2
3. No Notice	0	0	3

Note: "0" indicates no cost, "1" indicates lowest cost, etc.

A discussion of customer contact in isolation from the supplemental reporting and confidentiality issues is difficult. Therefore, in this discussion of customer contact, it is assumed that EPA can obtain supplemental information if it desires, and that confidentiality provisions sufficient to protect confidential data from disclosure have been adopted. That changes in these assumptions could alter the conclusions, however, must be recognized.

EPA Costs

Obtaining a Customer List. In some options, EPA must obtain a customer list from the producer before contacting customers. From the experience gained in processing the notices submitted thus far, and from industry comments, producers appear to be reluctant to identify customers. As a result of this reluctance, EPA may have to spend time negotiating with producers. Because EPA anticipates that the majority of its attempts to contact customers will be associated with those substances which it chose to review in detail (about 20 percent of the total), and because the amount of time devoted to interaction with the producer should not be great, the cost of obtaining customer lists should be minimal.

There are no added costs to EPA under Options 1 and 4, because the customer list is already provided. Under Options 2 and 3, the costs of persuading chemical producers to provide customer lists should be small, since customer lists will be requested only about 20 to 25 percent of the time.

Contacting the Customers. Under some options, EPA will incur the direct cost of contacting customers. The resources that EPA expends in contacting customers depends to a certain extent on the degree to which customers voluntarily provide information. Customer contact is anticipated to occur in only about 20 percent of all cases and EPA suggests that phone conversations with the customers should last about 30 to 45 minutes, so this expense should not be a major one.

The cost of contacting customers under Option 1 will be less than the costs under the other options at any given level of cooperation on the part of customers. Under Option 1, EPA will not have to expend resources to collect information on those customers willing to respond on the initial customer contact form.

Processing the Information. EPA will devote resources to evaluating the information obtained from the customers.

Under Options 2, 3, and 4, EPA will obtain information from customers in a maximum of 20 to 25 percent of the cases. Discussions with Agency personnel suggest that the cost of processing this information will be relatively small.

Under Option 1, EPA will receive information from customers in all cases (depending, of course, on the degree to which customers provide information voluntarily). This suggests that processing costs under Option 1 would be four to five times greater than under the other options. EPA could disregard the information gathered for those chemicals which do not undergo detailed review, thereby reducing its costs under Option 1 to the same level as for the other options.

The Option-Cost matrix in Exhibit D-6 displays the relative costs to EPA of the Customer Contact Options.

Society Costs

In accordance with each option, coverage and the type of customer information submitted are used to rank the five options in terms of unreasonable health and safety risks. In theory, the more information that is available, the better the decision EPA and the public will make; and the less likely it is that dangerous chemicals will be mistakenly distributed in commerce, and that safe chemicals will be mistakenly restricted. Therefore, the inclusion of as broad a range of information from customers as possible will increase the probability that a good decision is made.

Assuming that under Options 2, 3, and 4, the Agency would contact customers in all cases in which it felt their information to be necessary, these three options are ranked equivalently. Within the parameters of Option 1, customer information would be obtained in all cases, resulting in more information available to EPA. Presumably, this would enhance the possibility of a good decision by EPA. It should be noted that if EPA contacts customers in accordance with Options 2, 3, and 4 whenever necessary and is able to obtain the same information submitted by use of Option 1, then the useful information available in accordance with Options 1, 2, 3, and 4 would be the same. Option 5, by which use EPA is prevented from obtaining any information through customer contact provisions of section 5 of TSCA, would incur the highest society cost in terms of the quality of a decision.

It is possible to devote so many resources to evaluating the safety of new chemicals, delaying their introduction up to 180 days, and consuming society's scarce evaluative resources, that more harm than good is done to society by the evaluation process. Therefore, the cost to society in terms of foregone chemicals will be assessed. In terms of foregone chemicals, the use of Option 1 results in the highest costs. Option 1 involves processing customer information in all cases, and possibly delaying chemicals needlessly as a result. Options 2, 3, and 4 may involve some delay in processing chemicals through the customer contact procedure; however, the vast majority of cases in which EPA would request information from customers by use of Options 2, 3, and 4 would involve chemicals it chose to review in detail. Option 5 will result in no foregone chemicals.

The only difference between Options 2 and 3 is that in accordance with Option 3, the submitter is required to indicate on the notice form the estimated number of customers for all categories of use, including unknown

EXHIBIT D-6

THE RELATIVE COSTS OF CUSTOMER CONTACT OPTIONS

Option / Cost	EPA Cost 1 (Obtaining List)	EPA Cost 2 (Contacting Customers)	EPA Cost 3 (Processing Information)	Society Cost (Quality of Decision)	Society Cost (Foregone Chemicals)
1. January 10 Proposal (Contact All Customers)	0	1	2	1	3
2. October 16 Proposal (Contact Customers With Firm Orders)	1	2	1	2	2
3. Provision of Estimated Number of Customers	1	2	1	2	2
4. Provision of Potential Customer List	0	2	1	2	2
5. Elimination of All Customer Contact Provisions	2	3	0	3	1

Note: "0" indicates no cost, "1" indicates lowest cost, etc.

categories; by use of Option 2, the number of customers for unknown uses would be estimated only. Thus, the difference in cost between Options 2 and 3 is trivial. As a result of this small difference, these options are ranked equivalently according to EPA and society costs. Exhibit D-6 summarizes the relative costs of the Customer Contact Options.

INSUFFICIENT SUBMISSIONS

Section 5 of TSCA requires that a notice contain information and meet standards as prescribed in the Act. If submissions fail to meet these standards, EPA informs the submitter of the deficiencies and establishes the framework within which the submitter can correct the deficiencies.

Options

We have analyzed these four policy options associated with insufficient submissions:[8]

Option 1: January 10 Proposal--major deficiencies result in notice period not starting.

Option 2: modified January 10 Proposal--major deficiencies result in notice period not starting but submitter can appeal agency finding.

Option 3: deletion of general insufficient notice provisions from rules but agency can on case-by-case base determine individual submission insufficient.

Option 4: no insufficient notice provisions.

These options will be analyzed according to the relative costs they impose on EPA and on society.

The costs of Options 3 and 4 are difficult to assess, because they are heavily dependent on the behavior of the industry. In addition, the lack of rules under Option 3 and Option 4 means the industry will face considerable uncertainty until EPA establishes a pattern of behavior. Thus, the costs of Options 3 and 4 depend on EPA's behavior, as well as on industry's behavior. The uncertainty associated with these options makes the estimation of their relative costs difficult.

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[8] Complete descriptions of these four options can be found in: "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II - Issue Papers, Chapter 7-Insufficient Submissions (Washington, D.C.: ICF Incorporated, September 1980).

EPA Costs

Costs of Persuading Submitters to Voluntarily Correct Deficiencies. In accordance with Options 1, 2, and 3, EPA can refuse to accept a section 5 notice (the criteria vary among the options). By use of Options 2 and 3, EPA can only persuade the submitter to correct deficiencies voluntarily. This persuasion entails an expenditure of resources on the part of EPA. According to Option 1, the correction can be mandatory or the Agency may refuse to review the submission immediately.

Because the level of authority varies according to Options, EPA would incur costs trying to persuade firms to correct their submissions by use of Options 2 and 3, whereas by using Option 1, there would be no persuasion costs. If the relatively high level of voluntary compliance experienced thus far indicates the compliance level that will be achieved after final regulations are promulgated, persuasion costs using Options 2 and 3 are likely to be low.

Under Option 4, EPA may also use persuasion to convince the submitter to correct deficiencies. If Option 4 is used, the resources devoted to persuasion are likely to be greater than if Options 2 and 3 are used. By using Option 4, the agency must persuade the submitter to correct all deficiencies, whereas under Options 2 and 3 EPA must persuade the submitter to correct only minor ones.

Cost of Hearing Appeals. Under Option 2, submitters may appeal the Agency's determination that a submission is insufficient. EPA must expend resources to review the appeals. If the high degree of voluntary cooperation on notices submitted thus far indicates the degree that will be achieved after final regulations are promulgated, it is not likely that the frequency of appeals will be great. The possibility of an adjudicatory hearing in response to Option 2 use is an additional cost to consider.

Cost of Section 5(e) Action and Supplemental Reporting. Using Option 4, the remedies available to EPA would be to request information according to the proposed supplemental reporting provisions or by taking action in accordance with section 5(e) of the Act. The costs of supplemental reporting are discussed in the next section of this Appendix. In addition, the next section includes a description of the significant costs to EPA imposed by taking action under section 5(e). The provision in Option 1 for suspension of the notice period until the deficiency is corrected would be less costly to EPA than taking action in accordance with 5(e). Exhibit D-7 displays the relative costs to EPA of the four options.

Society Costs

The intent of the section 5 notice requirements is that EPA, with the assistance of the public should be able to judge whether or not a chemical is potentially harmful. The more time that is available to society to evaluate the information provided by the notice process, the better that judgment should be. TSCA specifies a 90-day period plus a possible 90-day extension as the time allowed for evaluation. The options will be evaluated in terms of how the notice period is altered under each of the options.

According to Options 1, 2, and 3, the initiation of the review period can be delayed if the submission is found to have major deficiencies (the initiation of the review period can be delayed for minor deficiencies as well using Option 1).

One reason for delaying the initiation of the review period is that the submission contains deficiencies so severe that the chemical substance cannot properly be evaluated. If this were so, and if the notice period clock were not set back to the beginning pending receipt of corrections, those evaluating the notice (EPA and society) might not have the time necessary to do a proper evaluation.

In accordance with Option 1, the clock is suspended for minor deficiencies. Therefore, some delays in the initiation of the review period using Option 1 may not be necessary to provide EPA and society with the full TSCA mandated review period. Under Option 2, the clock is not stopped for any reason. Thus, there will be no delays in the initiation of the review period for minor deficiencies.

By using Option 3, delays in the initiation of the review period would result if EPA determines that a notice is incomplete. No well-designed guidelines would exist for doing so. Therefore, no *a priori* assessment can be made as to whether delays occurring under Option 3 would provide society with the full TSCA-mandated review period.

Similarly, Option 4 presents uncertainties to society, and costs for this option are difficult to assess. The relative costs of insufficient submissions options are reviewed in Exhibit D-7.

SUPPLEMENTAL REPORTING

In evaluating the danger a new chemical substance poses for public health, EPA may require information other than that contained in the initial notice submission.

EXHIBIT D-7

THE RELATIVE COSTS OF INSUFFICIENT SUBMISSIONS OPTIONS

Cost / Option	EPA Cost 1 Persuasion	EPA Cost 2 Hearing Appeals	EPA Cost 3 Section 5(e)	Society Cost Review Period
1. Major Deficiencies Result in Notice Period Not Starting	0	0	1	2
2. Same as 1 with Appeal	1	1	0	1
3. Case-by-Case	1	0	0	0
4. No Provisions	2	0	2	0

Note: "0" indicates no cost, "1" indicates lowest cost, etc.

Options

We have analyzed three policy options for supplemental reporting. They are:[9]

- Option 1: January 10 proposal-- supplemental data can be requested;
- Option 2: October 16 proposal--specific supplemental data can be requested; and
- Option 3: No supplemental reporting rule.

Each of these options will be evaluated according to the costs imposed on EPA and on society.

EPA Costs

The costs of the supplemental reporting provisions to EPA are dependent on the behavior of the chemical industry in response to the regulation. The greater the voluntary cooperation on the part of industry, the less EPA will have to use formal procedures which consume more of the agency's resources.

Obtaining the Information: Because firms cannot be required to provide information by use of Option 3, EPA may make some effort to persuade firms to provide the desired information. Initial requests would be made for voluntary submissions. If the information is not provided voluntarily, EPA can initiate a section 5(e) action if the criteria for such an action are met.

Taking action under section 5(e), however, requires a large commitment of resources by the Agency.[10] In order to take action under section 5(e), the Administrator must find that the information available is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance, and either:

(1) that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury to health or the environment, or

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[9] Thorough descriptions of these three options can be found in: "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II - Issue Papers, Chapter 6-Supplemental Reporting (Washington, D.C.: ICF Incorporated, September 1980).

[10] Conversations with EPA staff.

(2) that the chemical substance is or will be produced in substantial quantities, and the substance enters, or may be reasonably anticipated to enter the environment in substantial quantities, or there is or may be significant or substantial human exposure to the substance.

The burden of establishing these findings imposes significant costs on the Agency.

Other Potential Costs. Under Options 1 and 2, EPA will still make an initial request for voluntary submission. If the needed information is not provided voluntarily, EPA will be able to pursue paths other than initiating a section 5(e) action, thereby incurring different costs. These different costs include:

- Preparing Justifications for Requests for Supplemental Information.

  By using Options 1 and 2, EPA must make certain findings before it can request supplemental information; additionally, EPA must send a statement of the findings, along with a detailed description of the information, to the person from whom the information has been requested.

- The Appeal Process

  By using Option 2, EPA must review appeals to requests for supplemental information.

- Cost of Processing Information

  EPA must expend resources in processing and evaluating the information received. These costs presumably are proportional to the amount of information received.

Analysis of EPA Costs: The costs to EPA for each information request using Option 3 would be somewhat greater than those costs using Option 1. When using Option 2, EPA would have to prepare a statement of findings that would be sent along with each request for supplemental information, and would have to hear appeals to its requests for information; neither of these are necessary under Option 1. If the appeal process resulted in an adjudicatory procedure, the costs to EPA of Option 2 in relation to Option 1 would increase significantly.

It should be noted that the additional cost of preparing a statement of findings using Option 2 should reduce the number of requests for information made by EPA. [Information that has a marginal benefit just equal to or less than the marginal cost of gathering and processing using Option 2 should not be sought, thereby decreasing total processing costs.] Whether this will be enough to offset the increased cost per request is unclear.

Using Option 3, there are no costs of appeals or providing justification, but EPA incurs the cost of persuading firms to supply information that is not supplied at the first request. The amount of information provided EPA by use of Option 3 will be less than when Options 1 and 2 are used, and the cost of processing and evaluating it will be less. Using Option 3, EPA may also incur costs of section 5(e) actions that the Agency would not incur using Options 1 and 2.

Exhibit D-8 summarizes the relative costs to EPA of the supplemental reporting options.

Society Costs

Quality of Notice Decision. From the standpoint of society, the least costly option is the one which minimizes:

1) the probability of a toxic substance entering commerce, and

2) the number of non-dangerous foregone chemicals.

For this analysis, the costs to society are based on the quality of a notice decision; the quality of a notice decision presumably is proportional to the amount of information available to EPA. (The more information that is available to EPA, the better the decision will be.)

Analysis of Society Costs. There will be slightly less information available by using Option 2 than by using Option 1, both because EPA will request less information and the industry may win some appeals. Option 2 will result in EPA making decisions based on less information and lower quality information than that available using Option 1. Thus, Option 2 is ranked higher in costs to society than Option 1.

The differences between the use of Options 1 and 2 and the use of Option 3 are dependent on the degree to which industry voluntarily complies with requests for supplemental information. At one extreme, if firms comply with every request for information, there is no difference in costs among the options. At the other extreme, if the firms refuse all voluntary requests, the cost differences are maximized. Industry spokesmen assert that the information will be voluntarily provided in the majority of cases.[11] If the number of recalcitrant firms is small, the costs of Options 1 and 2 should be low, and the difference between these two and Option 3 should be small.

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[11] Comments of the Chemical Manufacturers Association on EPA's Reproposal of Forms and Rules for the Submission of Premanufacture Notices Under Section 5 of TSCA, November 30, 1979, pp. 36-37.

EXHIBIT D-8

THE RELATIVE COSTS OF SUPPLEMENTAL REPORTING OPTIONS

Cost / Option	EPA Cost 1 Preparing a Justification	EPA Cost 2 Obtaining Information	EPA Cost 3 Hearing Appeals	Society Cost Quality of Notice Decision
1. January 10 proposal. Supplemental data can be requested	2	1	1	1
2. October 16 proposal. Specific supplemental data can be requested	3	1	3	2
3. No rule	1	2	1	3

Note: The option with the highest number (i.e., 3) has the highest relative cost. Where there are no significant differences in the costs imposed by the options, they are equally marked.

Source: EPA guidance; Industry and Public Interest group proposal comments.

Under Option 3, uncertainty exists over whether or not vital information will be made available by industry. As a result, it is more likely that EPA will lack the necessary information to make a good decision under Option 3 than under the other two options.

As illustrated in Exhibit D-8, Option 3 represents the greatest society costs, and Options 2 and 1 represent successively lower society costs.

THE CONFIDENTIALITY OPTIONS

The issue of which notice information is confidential and how it should be handled is addressed by a set of options specified by EPA. There are competing interests affected by the treatment of confidential business information. On the one hand, industry's interest in maintaining the confidentiality of business and trade secrets is based on the competitive advantage it derives from its work. On the other hand, society has a clear interest in obtaining information about chemicals so that potential harmful exposures and misuses can be avoided.

Subissues

EPA has specified policy options for the confidentiality issue according to subissues:[12]

- Methods of Assertion and Substantiation
- Timing for Substantiation;
- Generic Masking Options; and
- Options for Disclosing Chemical Identity (ID) as Part of a Health and Safety Study.

These subissues will be analyzed separately in terms of the costs they impose on EPA and on society. The costs attributed to the various options were derived from industry comments on the proposal and reproposal, and ADL estimates derived for the reproposal.[13]

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[12] Thorough descriptions of these options are found in "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II - Issue Papers, Chapter 1 - Confidentiality (Washington, D.C.: ICF Incorporated, September 1980).

EPA Costs. There is one EPA cost considered in this analysis: administrative costs. EPA must process notices, decide about the adequacy of confidential substantiation, consult with submitters, and so on. All of these activities consume the time of EPA staff, and the more activities there are, the greater the administrative cost to EPA.

Society Costs. The TSCA confidentiality policy entails costs for society as well as for EPA. TSCA's primary purpose is to strengthen the government's ability to protect the public from the hazards of toxic chemicals.[14] This purpose is achieved, in part, by permitting the public to participate in the review of a new chemical's effect on humans and the environment. It is necessary for the public to have information about the new chemical if meaningful public participation is to occur. The confidentiality policy, however, may block the public's access to information that would be helpful, or even crucial, to meaningful review of a new chemical. Insofar as the confidentiality policy has this effect, it imposes a cost or leads to costs that the public otherwise would have avoided. The costs should not be considered insignificant, because there is at stake the possibility of permanent and disabling injury to humans and long-term degradation of the environment. A labor union may be unable to warn its members of precautions that should be taken in dealing with a certain chemical, a citizens' group may be handicapped in learning about and preventing a particular use of some chemical which seriously damages the environment. Although many of the costs imposed are types which traditionally have been difficult or impossible to evaluate in monetary terms, the importance of these costs should not be underestimated. Finally, public costs can be imposed on society in general or on particular institutions representing public interests (for example, labor unions or public interest groups). Three costs to the public are considered in the analysis.

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[13] Comments of the Manufacturing Chemists Association on EPA Proposed Regulations for Premanufacture Notification Under Section 5 of TSCA (hereafter: MCA proposal comments), March 26, 1979; Comments of the Chemical Manufacturers Association on EPA's Reproposal of Forms and Rules for the Submission of Premanufacture Notices Under Section 5 of the Toxic Substances Control Act (hereafter: CMA reproposal comments), November 30, 1979; EPA's Interim Policy (44 Federal Register 28564-28572); EPA's Reproposal (44 Federal Register 59764-597-83); and Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, September 1979 (hereafter: A.D. Little Study).

[14] TSCA, Section 2(b)(2) indicates: "It is the policy of the United States that adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards."

- Cost 1: Probability of being denied access to information to which the public is entitled. A certain amount of information is necessary before an adequate public review can be made of the harm, if any, posed by a new chemical substance. This threshold may not always be met because Congressional policy generally forbids public disclosure of Confidential Business Information (CBI), and CBI may include information important to review of a chemical's toxicity. This does not mean that the public is left unprotected. EPA receives and evaluates all relevant information including CBI, and has the authority to take appropriate action to safeguard human health and the environment. Nevertheless, there also may be information to which the public ordinarily would have access, but is denied through some oversight or misjudgment. There seems to be at least one contributing factor to this cost: the rigor of confidentiality reviews may tend to decrease as EPA's limited resources are occupied with increased administrative duties.

- Cost 2: Time delay. The timing of public disclosure of information can often be as important as the substance of the disclosure. If information is not received in time to avoid exposures (human or environmental) to harmful substances, then when disclosure does occur it is of limited use. If information is revealed to the public during the 90 day review period, the public can participate in the review process. Thus, failure to obtain timely disclosure is a significant cost to society. This cost also may have a synergistic relation to EPA's administrative burden.

- Cost 3: Out-of-pocket expenses. This cost would normally be incurred by those institutions which represent the public interest. For example, a public interest group may institute legal action to compel EPA to disclose information. Such action may require substantial expenditures. Any option selected by EPA which makes it more difficult for the public to obtain information will increase the out-of-pocket costs for society. It should be recognized that if out-of-pocket expenses become too great, it may boost the extent of the other two public costs as well.

Methods of Assertion and Substantiation

The options associated with this subissue include:[15]

- Option 1: Assert item by item; substantiate by responding to a series of questions.
- Option 2: Assert by categories and linkages; substantiate by making a general certification (which would cover manufacturer's ID),[16] answering a series of questions for specific chemical ID and "other" information, and answering no more than two questions each for use data, process, mixture, and production information.[17]

EPA Costs. Neither option involves clearly lower relative costs for EPA's administrative efforts.[18] The same kind of substantive material is required to be submitted by both options; however, Option 2 involves less duplication in confidentiality claims, and requires submitters to focus on the key elements in EPA's determination of whether an item should be accorded the confidential status claimed by the submitter. This facilitates EPA's review process. On the other hand, the industry has intimated that the linkage system will require the submitter to provide considerably greater amounts of material to EPA than would be the case using Option 1. If so, EPA would have to review this greater quantity of material, thereby increasing its relative administrataive cost. Neither option, therefore, can be said to present a clearly lower cost alternative in terms of EPA administrative expenses.

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[15] For a complete description of the subissues and policy options, see "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II - Issue Papers, Chapter 1-Confidentiality (Washington, D.C.: ICF Incorporated, September 1980).

[16] This certification also would cover confidentiality claims for use data, production volume, and process information if neither manufacturers' identity nor chemical identity have been claimed confidential.

[17] These questions must be answered only if manufacturer's identity or chemical identity is claimed and held confidential.

[18] Industry claims the reproposal assertion and substantiation requirements are more onerous than the proposal (CMA reproposal comments, p. 99), while EPA claims these requirements avert duplication (Reproposal, 44 Federal Register 59774).

Society Costs.

- Cost 1: Option 2 lowers the cost to society by reducing the probability that information to which the public is entitled will be withheld. Option 2 requires the submitter to make clear the association between an item of information claimed confidential and the category under which it is claimed confidential. Option 1, on the other hand, involves only a general substantiation of a category of confidentiality, and does not require the submitter to focus on the link between a piece of information and the alleged harm its disclosure would bring. Option 2, therefore, minimizes the risk that the public will be denied access to information that was unnecessarily included in an assertion of confidentiality.

- Cost 2: Neither option presents a clearly lower relative cost in terms of reducing delay in the public's access to information. In general, these two options affect how the submitter will assert and substantiate a claim of confidentiality, not the timing of disclosure.

- Cost 3: Option 2 may involve a lower relative cost than Option 1 in terms of reducing the public's out-of-pocket expenditures. Insofar as the second option reduces the information improperly withheld from the public (see above), it also reduces the public's cost of trying to obtain the information which should not have been granted confidential status.[19]

The relative costs of the two options are summarized in Exhibit D-9.

Timing of Substantiation

Perhaps more than the question of how to substantiate, the issue of when to substantiate presents clearly defined alternatives with certain costs. EPA presented four options to be considered for analysis.

- Option 1: Requires substantiation only upon request from EPA.

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[19] There is not necessarily a one-to-one relationship between this cost and the cost of improperly withholding information. If information is withheld, it is less likely that the public will be aware of the relevance of the information to a confidentiality claim. In such a situation, out-of-pocket costs may be minimized simply because the public is unaware of which disclosure it should be seeking.

EXHIBIT D-9

THE RELATIVE COSTS OF OPTIONS FOR ASSERTING AND SUBSTANTIATING CONFIDENTIALITY

Cost / Option	EPA Cost Administrative	Society Cost 1 Withhold Information	Society Cost 2 Delay Access to Information	Society Cost 3 Out-of-Pocket Costs
1. Check-off Series	1	2	1	2
2. Linkage/ Reproposal Questions	1	1	1	1

Note: A "1" indicates the least costly alternative. Where there are no clear differences in the costs imposed by the options, they are equally ranked.

- Option 2: Requires substantiation when the notice is submitted for chemical ID, and health and safety study data; substantiation of all other information upon request.
- Option 3: Requires substantiation of section 5(d)(2) notice information when notice is submitted; substantiation of all other information upon request.
- Option 4: Requires substantiation of all confidentiality claims when notice is submitted.

EPA Costs. The administrative costs to EPA are minimized by Option 1 and maximized by Option 4.[20] It is certain that Option 1 initially involves a lower administrative burden than any of the other options, simply because EPA would have less information to review. On the other hand, if there were many Freedom of Information Act (FOIA) requests or other reasons for requiring subsequent substantiation, EPA would experience efficiency losses in reviewing the information in a piecemeal fashion. The efficiency difference between options, however, is not known. Therefore, the point at which it becomes less efficient to provide piecemeal substantiation, as opposed to substantiation with the notice, is unclear. Whether or not that point is crossed depends upon the amount of subsequent substantiation that is required.[21] Thus, based on the limits of present knowledge, Option 1 represents the smallest administrative burden for EPA, and Options 2, 3, and 4 represent successively greater administrative burdens.

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[20] The industry has suggested that EPA's attitude toward substantiation at the time of submission of required material has not been the Agency's historical stance. (See CMA reproposal comments, p. 118, footnote 3.) EPA's estimate that administrative savings will result if substantiation is submitted with the notice is based on an assumed high percentage of FOIA requests for submitted notices' confidential material (44 Federal Register 59775).

[21] For example, if there is one item of information each under manufacturer's identity, chemical identity, and use data that is claimed confidential, initial administrative costs obviously are lower if EPA does not have to review substantiations for the three claims when the notice is submitted. In the long term, however, substantiation may become necessary for some or all of the claims. Because there is some minimum administrative effort required to review the substantiation, whether submitted with the notice or later, it is not necessarily more costly for EPA to review one substantiation not submitted with the notice than to review three substantiations with a notice. A similar conclusion is reached about two subsequent substantiations compared to three substantiations submitted with the notice. The only definitive statement that can be made is that, using Option 1, EPA's administrative costs will be higher if EPA must subsequently review all the substantiations that would have been submitted with the notice using one of the other three options. The above example is simplistic, but it illustrates the uncertainty of what long-term administrative advantages actually will accrue to EPA if some or all substantiation is required to be submitted with the notice.

Society Costs.

- Cost 1: Relative to the other three options, Option 1 raises the cost to the public by increasing the probability that information to which the public is entitled will be withheld. If the submitter can delay in providing substantiation (which is permitted in varying degrees by Options 1, 2, and 3), information claimed confidential (but not necessarily to be accorded confidential status when appropriate substantiations are reviewed) will be withheld from the public until a request (at the instigation of EPA or the public) for substantiation is made. This failure to provide substantiation when the notice is submitted may result in public ignorance of information to which the public could have gained access. On the other hand, it may be that substantiation submitted with the notice will no longer be accurate when a subsequent request for the protected information is made. If EPA relies on the outdated substantiation to deny disclosure of the information, the public would unnecessarily have been denied access to information.[22]

  Thus, if substantiation upon request (which is present in varying degrees in Options 1, 2, and 3) had been utilized instead of substantiation with the notice, information would not have been withheld from the public. This latter situation which postulates an out-of-date substantiation seems less likely and more easily remedied than the former situation postulating public unawareness. Similarly, the level of cost seems higher for the first situation, because it may unnecessarily prevent effective public participation in the review notice, while the second situation suggests denial of information at some later date when effective review participation no longer is possible. Therefore, Option 1 represents the greatest cost to the public in terms of probable withholding of information to which the public is entitled; in general,[23] the other three options, 2, 3, and 4, are successively less costly.

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[22] CMA reproposal comments, pp. 123-124.

[23] There may be particular situations where one specific item of information is most important--for example, production volume. Because only Option 4 requires that substantiation of this information be submitted with the notice, Options 1, 2, and 3 are equally costly (in this instance) in terms of withholding public information. As a general rule, however, the more confidential claims that are not substantiated with the notice, the greater is the public cost in terms of withheld information.

- Cost 2: Option 1 involves the highest relative costs in terms of delay in providing the public with information, and Option 4 involves the lowest relative costs in these terms.[24] Substantiation submitted with the notice enables EPA to determine the validity of confidentiality claims early in the review process. This, in turn, enables EPA to disclose information at an earlier time than if the substantiation could be obtained from the submitter only on request. Similarly, substantiation submitted with the notice enables EPA to give more timely notice to requestors of confidential information that the information is unavailable. These requestors can then take whatever action is necessary from their standpoint without experiencing the delays inherent in the substantiation-by-request situation. Therefore, as more confidentiality claims are substantiated with the notice, this particular cost is minimized. Option 4 represents the lowest relative cost in terms of delay in release of public information, and Options 3, 2, and 1 represent successively higher relative costs.

- Cost 3: Option 4 involves the lowest relative cost in terms of public out-of-pocket expenses, and Option 1 represents the highest relative cost in these terms.[25] One of the ways that the public may obtain information not disclosed by EPA is by some group acting in the public interest to institute FOIA proceedings. This involves out-of-pocket expenditures on the part of the public interest group. When more information is disclosed as a result of EPA's review of the notice, there is less necessity for these FOIA proceedings and the accompanying out-of-pocket costs to the public.

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[24] Industry suggested that delay would not be serious if FOIA request frequency were low (CMA reproposal comments, p. 133). Nevertheless, all information claimed confidential, but subsequently determined by EPA not to be confidential, should have been available to the public when it was submitted. Failure to substantiate with the notice submission delays EPA's determination of confidentiality and delays the public's access to the information (see Federal Register 59774-59775). Of course, this latter point assumes there will be some information erroneously claimed confidential.

[25] See 44 Federal Register 59775. Substantiation submitted with the notice makes it more likely that information not entitled to confidential treatment will "be made available to the public during the 90-day notice period." This could save the public the expense of unnecessary FOIA requests.

Option 4 enables EPA to make the broadest determination of confidentiality, thereby facilitating more disclosure of non-confidential material than the other three options and reducing the level of public out-of-pocket costs. The other three Options, 3, 2, and 1 represent successively lesser amounts of non-confidential information disclosure and correspondingly higher public out-of-pocket costs.

The relative costs of the form options are summarized in Exhibit D-10.

Generic Masking Options

In some instances when a confidentiality claim is asserted, the submitter would be required to substitute a generic name or information to replace the confidential information. Three generic options have been considered and are described below.[26]

- Option 1: January 10 Proposal--Requires generic name if chemical identity or use data is claimed confidential.
- Option 2: October 16 Reproposal--Requires considerable generic information if confidentiality is claimed for chemical identity, use data, physical and chemical properties, or manufacturer's identity.
- Option 3: No Generic Information.

EPA Costs. Option 3 imposes the lowest relative administrative costs for EPA.[27] EPA's resources must be expended in evaluating the submitter's generic information--whether at the pre-notice consultation stage or when the notice is submitted. The less information that EPA has to review, or the less time EPA has to devote to negotiating generic information, the lower the cost of an option to EPA in terms of administrative expenditures. Option 3 would require the submission of no generic information and, consequently, represents the lowest relative administrative costs for EPA. Using Option 2, EPA is required to evaluate more specific information than under Option 1, and also may have to compose the generic description for three of the four generic items. Option 2, therefore, is relatively more costly to EPA in terms of EPA administrative resources.

Society Costs.

- Cost 1: Option 2 represents the lowest relative public costs in terms of the amount of information which will be withheld. Because of the requirements of confidentiality, the public potentially will be denied access to information which is useful in

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[26] These options are described in detail in "Economic Impact Analysis of Proposed Section 5 Notice Requirements," Part II - Issue Papers, Chapter 1 - Confidentiality (Washington, D.C.: ICF Incorporated, September 1980).

[27] See CMA reproposal comments, pp. 104, 151, 155-157.

EXHIBIT D-10

THE RELATIVE COSTS OF OPTIONS FOR TIMING SUBSTANTIATION

Option \ Cost	EPA Cost Administrative	Society Cost 1 Withhold Information	Society Cost 2 Delay Access to Information	Society Cost 3 Out-of-Pocket Costs
1. Nothing with Notice	1	4	4	4
2. Chemical ID and Health and Safety Data with the Notice, the Rest on Request	2	3	3	3
3. 5(d)(2) Information with the Notice, the Rest on Request	3	2	2	2
4. Everything with the Notice	4	1	1	1

Note: A "1" indicates the least costly alternative. Where there are no clear differences in the costs imposed by the options, they are equally ranked.

Source: CMA reproposal comments; EPA reproposal comments; and A.D. Little Study.

reviewing the effects of a new chemical on humans and on the environment. Although Options 1 and 2 seek to redress this inherent problem of the confidentiality issue, Option 2 goes further in providing information for the public assessment of the new chemical. Instead of being limited to generic descriptions of a chemical's identity and its categories of use, Option 2 provides additional generic information about the identity of the manufacturer and the nature of the chemical's physical and chemical properties. This additional information enhances the public review of a chemical's toxicity. Option 3, which provides no generic information, clearly represents the most costly of the three options in terms of information withheld from the public.

- Cost 2: Neither Option 1 nor 2 has a relative advantage in avoiding the delay in releasing information to the public.[28] In accordance with both Options 1 and 2, pre-notice consultation is encouraged so that generic information release can be expedited. Option 3, which requires no generic submittals, has no effect on the delay costs.

- Cost 3: None of the three options has a distinct effect in lowering out-of-pocket costs for the public. The public cannot compel submission of generic information. Therefore, regardless of which option is selected, the public will not incur option-dependent out-of-pocket costs.

The relative costs of the three options for generic masking are summarized in Exhibit D-11.

Disclosing Chemical ID as Part of Health and Safety Study

If a health and safety study is submitted as part of the notice, the following subissues must be decided:

- timing options: when the chemical ID will be disclosed; and
- inventory options: how the chemical ID should be added to the inventory.

Timing Options

- Option 1: when the notice is submitted;
- Option 2: when manufacture begins; and
- Option 3: when the new chemical substance is distributed in commerce.

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[28] See the EPA comment regarding chemical identity and generic information, 44 Federal Register 59776.

EXHIBIT D-11

THE RELATIVE COST OF OPTIONS FOR GENERIC MASKING

Option \ Cost	EPA Cost Administrative Cost	Society Cost 1 Withhold Information	Society Cost 2 Delay Access to Information	Society Cost 3 Out-of-Pocket Costs
1. Chemical ID and Chemical Use	2	2	1	1
2. Chemical ID, Chemical Use, Manufacturer's ID, and Physical/ Chemical Properties	3	1	1	1
3. No Generic Information	1	3	0	1

Note: Higher numbers indicate higher relative costs. Where there are no significant differences in the costs imposed by the options, they are equally ranked.

Source: CMA reproposal comments; MCA proposal comments; EPA reproposal comments.

EPA Costs. EPA's costs are not significantly affected by which one of the three options is selected. There might be some minor administrative efficiency achieved if dislosure was in conjunction with receipt of the notice (i.e., Option 1); but disclosure itself is a relatively mechanical act and would require no additional evaluation, and later disclosure should involve little efficiency loss.

Society Costs.

- Option 1: The disclosure is earlier than the other two options, and the public receives the information for more timely input to its assessment of the chemical's potential effect on humans and the environment. Thus, the time delay cost is kept at a minimum.[29] Other public costs are not significantly affected by this set of options.

- Option 2 is between the other two options. Information is provided to the public more slowly than Option 1, but more quickly than Option 3. Thus, depending on the option to which it is compared, Option 2 either increases or reduces the cost to society in terms of delayed receipt of information.

- Option 3 imposes the highest costs for the public. Option 3 protects the chemical identity from disclosure longer than the other two options. This could result in disclosure more than six months after the Option 1 disclosure date. Those six months can be a period during which substantial advances could have been made in assessing the chemical's impact on humans and on the environment.

Exhibit D-12 displays the relative costs of timing options.

Inventory Options. The final set of options regards placement of chemical ID on the inventory.

Option 1: by specific chemical name; and

Option 2: by generic chemical name.

EPA Costs. Neither option involves lower relative costs for EPA's administrative efforts.

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[29] The importance of avoiding this time delay is emphasized by EPA. See, e.g., EPA comments in its Interim Policy announcement 44 Federal Register 28564 et. seq. at pp. 28567-28568, and EPA comments accompanying the reproposal, 44 Federal Register 59775.

EXHIBIT D-12

THE RELATIVE COSTS OF OPTIONS FOR TIMING THE DISCLOSURE OF CHEMICAL ID AS PART OF A HEALTH AND SAFETY STUDY

Cost / Option	EPA Cost Administrative Cost	Society Cost 1 Withhold Information	Society Cost 2 Delay Access to Information	Society Cost 3 Out-of-Pocket Costs
1. Disclose at Time Notice Submitted	1	1	1	1
2. Disclose at Time Manufacture Begins	1	1	2	1
3. Disclose at Time Distributed in Commerce)	1	1	3	1

Note: Higher numbers indicate higher relative costs. Where no significant differences exist in the costs imposed by the options, they are equally ranked.

Source: MCA (CMA) proposal comments; CMA reproposal comments; EPA comments accompanying the Interim Policy and the Reproposal.

Society Costs. The generic option would impose some costs on society calculated in terms of additional time delay in obtaining the information (i.e., specific chemical ID would be more readily available to the public as part of the inventory--an available, separate document) and in terms of the additional out-of-pocket costs to obtain the information (i.e., it will be more expensive to obtain the specific chemical ID from the public record than to obtain a single document--the inventory--with the desired information).

Exhibit D-13 illustrates the increased cost to society of the generic name option.

SUMMARY

The purpose of this report is to present to EPA a framework from which to evaluate these issues. The costs to EPA and to society involved with each of these issues are dependent on the regulatory option chosen, the way EPA implements the regulations, and the way industry responds to the regulations. The sensitivity of the costs to the uncertain behavior of both regulators and the regulated reduces the precision with which costs can be estimated. By estimating the cost differences among the options rather than absolute cost levels, we have minimized this problem. Nevertheless, in several parts of this report it was necessary to make certain assumptions about the behavior of parties towards the regulation. It should be noted that changes in these assumptions may affect the estimated cost rankings of the policy options.

EXHIBIT D-13

THE RELATIVE COSTS OF OPTIONS FOR PLACING CHEMICAL ID (CONTAINED IN A HEALTH AND SAFETY STUDY) ON THE INVENTORY

Option \ Cost	EPA Cost Administrative Cost	Society Cost 1 Withhold Information	Society Cost 2 Delay Access to Information	Society Cost 3 Out-of-Pocket Costs
1. Place on Inventory by Specific Name	1	1	1	1
2. Place on Inventory by Generic Name	1	1	2	2

Note: Higher numbers indicate higher relative costs. Options are ranked equally when no significant cost differences exist.